(b). Definitions. (1) "Subject Invention" thins any invention of the submitted and invention of the submitted any art, submitted any submitted any art, submitted any submitt

included to principal rights. (1) The collision of principal rights, the collision may redshift to entered the state of the collision may redshift to entered the state of the collision state of the collision state of the collision state of the collision of the collision state of the collision of the collision of the collision state of the collision of the colli

election.

(2) The Institution agrees to convey to the Covernment, upon request; the entire domestic right, title, and interest in any Subject investion when the Institution:

(1) Does not elect under paragraph (c)(1) to retain such rights; or (1) Parlia to have a fortied States Patent Application filed on the investion in accordance with paragraph (c)(1), or decides not to continue procedulon of such application;

(III) At any time no longer desires to etain title.

(3) The Institution agrees to convey to the Soverment, upon request, the entire right, like, and interest in any Subject Invention title, and interest in any Subject Invention the Institution:

(3) Does not elect under paragraph (c)(1)

der paragraph (c)(1)
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ir to pay any maintenance rees overting the biretidian. To sould outfilling of the plantin biretidian, and the plantin biretidian to the plantin biretidian period for any action and the paying the or plantin biretidian period for any action period for any action and the plantin biretidian period for any action and proceed the paragraphs (c)(2) or (3) of this Agreement, shall be made by diverting to the Agenty of the paying and proceed the covernment to upply for and proceed the covernment to upply for and proceed the covernment to upply for and proceed the state right, title, and interest to cauche the satisfaction overlag obtainty, respectively, or otherwise establish Government ownership of such investion to the united States a nonexclusive industrial patient plantin and the such action of the United States a nonexclusive industrial processor to make, use, and all each Subject Invention in the united States a nonexclusive industrial processor to the United States and onnestite manifold processor to make, use, and several parameter and processor to the United States and onnestite manifold processor to internate the major and processor to the United States and onnestite manifold processor to include the processor of the United States and onnestite manifold processor to internate the second payer of the transition of the processor of the United States and onnestite manifold processor to internate the second payer of the covernment of makes and onnestite manifold processor to describe the covernment of the processor of the processor of the covernment of the processor of the second that it is increased in the second that it is increased to acquire the internation to the covernment of the second that it is increased and onnestite manifold of the resident of the covernment of the second that it is increased in the second to the process subject to the forest the second that it is presented to the order of the covernment of the second to second the invention of the second to the process of payers of the second to seco

tion shall obtain patent ect the provisions of this all persons in its employ part of the work under

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Within 2 months after submission of the inwithin 2 months after submission of the inwithin 2 months after submission of the inwithin 4 months after submission of the inwestled disclere if the patent application
was filed prior to the contract, delirer to the
Agency (A) a copy of the application as
filed, including the filing date and serial
number, and (B) a copy of an assignment
from the inventor or hveniour to the insultitudin of all right, tide, and interest in the
filed including the filing date and serial
number, and the state of the interest of the
filed interest or popular vectored in the Subject invanion. "The Government's has rightly control of the responsion
and any patents issued on the Subject invanion, "The Government's has rightly the Agency or Agencies?"
(IV) Not ies than 30 days before the expiration of the response period for any section
required by the Office, healty the Agency or Agencies, The Agency of Agencies
to continue the prosecution of the significant of the seption to the section that the continue the prosecution of the section that the continue the prosecution of the section that the continue the prosecution of any patents' application and
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Invention on an exclusive basis if it determines that are recuisive because if it determines that an exclusive basis if it determines that an exclusive basis if it determines that an incentive for development of the invention of its previous betalation on a certainty because it is necessarily as an incentive for development of the invention of its previous betalation on a certainty basis in order to order the area of the brittlenth of the invention of the product of the product of the product of the product or process product or process not only an extension betalation of the product or process in the commercial and or use in the United for a limit of the commercial and or use in the Oblicial first commercial and or use in the Oblicial first order of the product or process embodying the invention, or 3 years from the Agency, screed of present or a production into the commercial market and the search of the product of process embodying the invention, or 3 years from the first the license shall use all reasonable business that because the search of the product of the commercial market, and market of the sound of the antiferrant and of the foreit introduction into the commercial market, and increase shall be of the search of the maximum period of the administrative that the license shall not normally be in excess of accepted frade practice. Orderment of the foreit introduction in the commercial market with a foreity interferent or any order or any extension order of the commercial market or any order order order order order order order order or any extension order order order order order order or any extension order ord

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(B. Reports on Development and Cormer-end The. The Institution shall provide a written strains report to the Agency on or before Developer 1 to the Agency on or the Agency of the Agency of the New July 1 to the Agency of the New July 1 to the Agency of the Commercial use that it are less man of the ton left for administration to the Institu-tion left for administration to the Institu-tion and the retop that have been taken by the Institution to bring the Institution to the Poble of practical application, it is also the Poble of practical application.

RULES AND REGULATIONS

by the Institution, and such other data and information as the Assucy may reasonably specify. To the extent data or information supplied to this section is considered by a licensee to be privipised or confidential and is so marked, the Agency agrees that, to the extent permitted by law, it will not disclose such information to persons outside the Government.

Government. (i) Reporting of Policy and Administrative Changes. The Institution shall promptly notify the Agency of any significant changes in the information submitted by it in support of its request for an Institutional Fatent Agreement; particularly, changes in paracter policies or its administrative expansion. hillitee

bilities.

(m) Termination. This Agreement may be terminated by either party upon 30 days written notice. Disposition of rights in and administration of inventions made under which notice. Spontent on rights in that administration of inventions made under contracts subject to this Agreement will not be affected by such a termination, except the effected by such a termination, except pates the Agreement because of a failure or refusal by the natitution to comby with any of its chigations under sections (c)(1), (1), and (1) of this Agreement because of a failure or refusal by the natitution to comby with any of its chigations under sections (c)(1), (1), and (1) of this Agreement, the Agreement of the Agreement of the Interest in and to the particular invention with respect to which the breach occurred be assigned to the United States of America, as represented by the Agreen's, (1) Communications. (8) Requests for Agency Sprovals, extendions, or similar ac-

(ii) Communications. (3) Requests for Agency approvals, extendions, or similar sections and other correspondence required by this Agreement, should be addressed to this Agreement, because the section of the control o

In witness whereof, each of the parties hereto has executed this Agreement as of the day and year below.

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	(Institution)
Evuin	A.—Confirmatory Instrument
vention).	tion for: (Title of Ir
	or(s) ————.
	No. — Contract (Gran

(specify Government agency)

was subject.

This document is confirmatory of the paid-up leaves granted to the Government moder this contract (great) in this invention, patent application, and any resulting patent, and of all other rights acquired by the Government by the referenced Agreement. (10)

It is understood and agreed that this document does not preclude the Government from asserting rights under the provisions from a from asserting rights under the provisions of said Agreement or of any other agree-ment between the Government and the Contractor, or any other rights of the Gov-ernment, with respect to the above-identi-fied invention.

fled invention.

The Government is hereby granted an irrevocable power to inspect and make copies of the above-identified patent application.

Signed this --- day of -(Institution)

(Signature)

(Print or type name)

(Official title) (End of Agreement)

(End of Agreement)

(1) Insert name of Agency.
(2) Insert reference to Institution's official policy statements.
(3) Some segencies may wish to have the agreement apply to all Stublect Inventions of the control of the control of the agreement apply to all Stublect Inventions of the agreement apply to the agreement in such cases of the following hanguage may be substituted.

"This Agreement defines the rights of the parties hereor regarding the allocation of rights in Subject Inventions reported after the execution of the Agreement, including contracts entered into prior to this Agreement, accept and the control of the Agreement, accept and the control as may be specified and the control of the Agreement such as the following contracts: even the agreement should add a statement such as the following contracts: even "(4) The bracketed language may be detend but normally it is expected that Institutional Factor Agreements will apply to the 150 Agreedes have agreements will apply to 150 Agreedes than agreements will apply to 150 Agreedes have agreements after the particular and the control of the contro

grants as well as contracts.

grants as well as contracts.

(5) Agencies may specify a form.

(6) Agencies may find it useful to include more detailed instructions here on the format of these reports and the persons to whom they should be supplied. The exact chairs may have to be varied according to the contract of the contract of

edures.
(7) If none are to be used, insert "none."
(8) Different dates may be substituted de-iending on the Agency's needs.
(9) Insert applicable addresses and offi-

cers. (10) in accordance with Section (dX1) of the Agreement, if the Agency has deter-mined that a license for State and domestic municipal governments will not be obtained, the following should be added to the Confir-

forey instrument;
The license granted to the Government s not include State and domestic munici-

nal governments. Section 1-9.109-7 is added as follows:

§ 1-9.109-7 Negotiation of institutional patent agreements.

(a) Information to be submitted by nonprofit organization. A nonprofit organization desiring to enter into an

Institutional Patent Agreement with an agency shall be required to provide the agency with the following information

mation;
(i). General information concerning
the organization including;
(i) A copy of the organization's Articles of Incorporation;
(ii) A statement of the organization's

(ii) A statement of the organization's purpose and aims; and (iii) A statement indicating the source of the organization's Indis; (2) A copy of the organization's established patent policy, together with the date and manner of its adoption; (3) The name, title, address, and telephone number of the officer responsible for administration of patent and invention matters and a describe and invention matters and a descrip-tion of staffing in this area, including all offices which contribute to the organizati bilities: zation's patent management capa

(4) A description of the organiza-tion's procedures for (A) identifying and reporting inventions and (B) for the evaluation of such inventions for inclusion in the organization's promo-

inclusion in the arguments of the tional program;
(5) A copy of the agreement signed by employees engaged in research and development, indicating their obligation with regard to inventions con-ceived or for the first time reduced to practice in the course of their assigned duties;

duties:

(6) A copy of the invention report form or outline utilized for preparation of invention reports;

(7) A statement indicating whether the organization has an agreement with any patent management organizations or expensions or expensions or expensions. zations or consultants and a copy of

zations of consumants and a copy of any such agreements; (8) A description of the plans and in-tentions of the organization to bring inventions to the market place to which it retains title, including a de-

which it retains title, including a description of the efforts typically undertaken by the organization to license its inventions.

(9) A description of the organization's past patent application and patent licensing activities, including the following:

(i) Number of inventions reported to the organization during each of the

the organization during each of the past 5 years; ...
(II) Number of patent applications flied during each of the past 5 years; (III) Number of patents obtained during each of the past 5 years; (IV) Number of exclusive licenses; issued during each of the past 5 years; (V) Number of nonexclusive licenses; other than those to sponsoring Federal agencies, issued during each of the nast 5 years;

al agencies, issued during each of the past 5 years; (vil) Gross royalty income during each of the past 5 years; (vil) A general description of royal-ties charged, including minimum and maximum royalty rates; (10) A list of subsidiary or affiliate organizations, which would be covered

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by an agreement signed by the organi-

by an agreement approximation is a subsid-ary or affiliate organization the name of the other organization and a description of the relationship;

(12) The amount of support from each Federal agency for research and development activities currently being administered by the organization;

auministered by the organization;
(13) A statement of the organization's policies with respect to the sharing of royalties with employees and
(14) A description of the uses made
of any net income generated by the organization's patent management program

(b) Criteria for evaluation of a techto criteria for evaluation of a term onlogy fransfer program. Before an Institutional Patent Agreement is entered into with a nonprofit organization, the organization shall have a technology transfer program which, as a minimum shall include: a minimum, shall include:
(1) An established patent policy

which is consistent with the policy in \$1-9.107-3 and is administered on a continuous basis by an officer or an organization responsible to the organi-

(2) Agreements with employees re-quiring them to assign to the organiza-tion, its designee, or the Government any invention conceived or first actually reduced to practice in the course of or under Government contracts or assurance that such agreements will be obtained from employees prior to the assignment of employees to Gov-ernment-supported research and de-velopment projects:

Procedures for prompt invention identification and timely disclosure to the officer or organization administering the patent policy of the institu-

(4) Procedures for invention evaluation; and (5) An active and effective promo-

tional program for the licensing and marketing of inventions.

(c) Federal Coordinating Council for Science, Engineering, and Technology List. A list of organizations that have Last. A list of organizations that have technology transfer programs meeting the critieria set forth in § 1-9.109-7(b), prepared by a subcommittee of the Committee on Intellectual Property and Information of the Federal Coordinating Council for Science, Engineering, and Technology, may be used in light of individual scenario deservation. neering, and Technology, may be used in lieu of individual sapeny determinations of eligibility for institutional Patent Agreements. However, the inclusion of an organization on the list will not preclude the sgency from declining an application for an institutional Patent Agreement. It is also expected that the list may be used by some agencies in connection with stream of the service of the inclusion of clauses in contracts giving the nonprofit forganicontracts giving the nonprofit organization the first option to principal

RULES AND REGULATIONS

rights in inventions made under the (Sec. 206(c), 63 Stat. 390; 40 U.S.C. 486(c).)

Nore.—The General Services Administra-tion has determined that this document. does not contain a major proposal requiring preparation of an inflationary impact Statement under Executive Order 11821 and OMB Circular A-107.

Dated: January 20, 1978.

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JAY SOLOMON, Administrator of General Services.

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Title 41-Public Contracts and **Property Management**

CHAPTER 1-FEDERAL PROCUREMENT REGULATIONS

[FPR Amdt. 187]

PART 1-9-PATENTS, DATA, AND COPYRIGHTS

Patents: Change of Effective Date

AGENCY: General Services Administration.

ACTION: Final rule: Change of effective date.

SUMMARY: The effective date of the Federal Procurement Regulations (FFR) Amendment 187 is changed from March 20, 1976, to July 18, 1978. FFR Amendment 187 was issued January 26, 1972, and was published in the ary 20, 1978, and was published in the FEDERAL REGISTER (43 FR 4424, February 2, 1978). The change of the effec-tive date for the amendment is based tive date for the amendment is based on a request of the Administrator, Office of Federal Procurement Policy.

DATES: effective date of this document: April 11, 1978; Revised effective date for FPR Amendment 187: July 18, 1978.

FOR FURTHER INFORMATION CONTACT:

Philip G. Read Director of Federal

Procurement Regulations, 703-557-2947. (Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c).)

Dated: April 11, 1978.

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JAY SOLOMON, Administrator of General Services.

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[FR Doc. 78-10830 Filed 4-20-78; 8:45 am] tinger Colonia (1942) and independent of the colonia of the coloni

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association of american medical colleges

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June 22, 1978

Live Charles Ast

Mr. Gerry Sturges c/o Senator Gaylord Nelson Russell Senate Office Building Washington, D.C. 20510

Dear Gerry:

It was a real pleasure to see you again on Saturday evening. I particularly enjoyed talking with you about Institutional Patent Agreements. As I told you sometime ago, we received from NIH a sampling of university patent licensing programs which we were asked to assess in terms of their value to society. We had considerable difficulty arriving at a mechanism for assessing "social value", nevertheless we thought the exercise might have some merit. Accordingly, on April 25, 1978, we sent out the attached list of patents to approximately 20 of our constitutents who might be reasonably knowledgeable in the areas covered. Enclosed is a copy of the memorandum which was sent to these scientists of whom approximately 15 responded. Most of the scientists were unfamiliar with many of the patents; however, we were able to get some rating of almost all of the patents on our list. We used a four interval scale with 0 being "no value" and 3, "great value".

The results have now been tabulated and may be interesting to you. If you would be interested I can summarize this information in some form that might be useful to you or the Committee. In summary, however, it appears that most of the patents which have been reduced to successful application are of "moderate" value regardless of how much money has been invested in their development.

I am also enclosing a copy of our recent Supreme Court Amicus Curiae brief in the case of Chrysler vs. Brown. Joe Keyes thought it might be of interest to you because it deals with the confidentiality issue and specifically with exemption B (4) of the Freedom of Information Act. Also, at John Sherman's urging, I am enclosing a copy of a recent AAMC staff position paper on the problems facing the peer review system at NIH. You will note that the Privacy Act may have apparently added the "final overload to the system", in that investigators are using the Privacy Act to obtain confidential reviews ("pink sheets") prior to completion of action on their grant request.

John, Joe and I would be pleased to talk with you further about this or related issues and will follow with interest the progress of your IPA hearings.

sincerely,

Thomas E. Morgan, M.D. Director, Division of Biomedical Research

Suite 200/One Dupont Circle, N.W./Washington, D.C. 20036/(202) 466-5100



association of american medical colleges

April 25, 1978

MEMORANDUM

TO:

Members of the CAS Administrative Board and CAS Public Affairs Representatives

FROM:

Thomas E. Morgan, M.D.

SUBJECT:

Evaluation of Certain Patented Inventions

The Department of Health, Education and Welfare is re-evaluating the Department's present policy toward institutional patent agreements (IPAs). The AAMC, working with the National Association of Land Grant Colleges and the Association of American Universities, is studying the problem. We hope to generate a position statement based on facts.

One of the factors in our appraisal of IPAs will be an assessment of how much value resides in those patents which have been brought to the marketplace. We would very much appreciate your taking a few mements to look over the enclosed list of patent awards for inventions arising out of biomedical research and noting, in the space provided, your assessment of the value of any of those inventions with which you are familiar.

We suggest you use the terms "great, moderate, minimal or none" to describe their actual or potential value. It is difficult to be specific about how to rate the term "value" but inventions might be judged on the basis of their economic, scientific and/or social or health care value. These appraisals should be made without regard to their economic return or impact but rather on their merit to, actual or potential, in patient care or scientific research.

If you have insufficient knowledge of any invention listed please so note. When you have completed the appraisal or if you cannot complete the form for any reason please fold, staple and return to us.

3 2 1 0 * Great, Moderate, Minimal, None

	SAMPLIN	G OF UNIVERSITY PATENT LICENS	ING PROGRAMS					. ry .
Inventor	University	Invention	<u>Licensee</u>	Approximate Investment	Value*		Vumber Opinius	
Walser	Johns Hopkins U.	Keto-Acid analogs of Amino Acids for treatment of	Germany and Syntex	Millions - Clinical trials in process. Expected to be	2.5		. 4	(2)
10 1 10 1	•	uremia	of U.S.A	marketed in 6 mos. in Europe.	£.		24	
Wiktor	Wistar Institute	Rabies Vaccine	Wyeth Laboratories	On the market - millions	2.0		7	
Kamen et al	Case Western Res.	Methotrexate Assay during Cancer: Chemotherapy	Diamond Shamrock Corp.	Being test-marketed. Production scheduled for late 1977. Millions.	2.0		- 5	1 \$ 13 14 14
Eillehei/Kaster	U. of Minnesota	Pivoting Disc Heart Valve	Medical, Inc.	Being sold in world-wide market since 1971. Millions.	1,5		4	
Blackshear et al	U. of Minnesota	Implantable Infusion Pump (Constant Infusion of Drug for Treatment of Cancer, Diabetes, Pain, Morphine- addiction, etc.)	Metal Bellows Co. S	Undergoing clinical trials. \$750,000.	2.0		8	
DeLuca	U. of Wisconsin	25-Hydroxycholecalciferol for treatment of Osteo- dystrophy with liver	Rousel-Uclaf (Hoechst) and	Have applied for equivalent of MDA in France. Approximately \$5 million.	। <u>इ</u>		4	
		dysfunction	Upjohn	About to apply for an NDA and an NADA. Will spend about \$10 million.				- 13. 4
DeLuca	U. of Wisconsin	1-Alpha Hydroxycholecalciferol for treatment of Osteo- dystrophy with Kidney	Leo Pharma- ceuticals	Applying for new drug applications in Denmark and Great Britain. May be marketed this year.	1,7	5 (1.8) (a)	新 ・ - - 特	
33		Dysfunction		Approx. \$5,000,000.		£1 .		

				11.42-43. 33.41 13.41 11.11		• GREAT, MODERAT	E, MINIMAL, HONE
41 X	Inventor	SAMPL University	LING OF UNIVERSITY PATENT LICES Invention		Approximate Investment	Value*∴	Opinions
ga ti	DeLuca et al	U. of Wisconsin	1, 25-Dehydroxyergocalci ferol for Treatment of Ostoodystrophy with Kidney and Liver Dysfunc and Senile Osteodystroph	inc. Substitution in the contract of the contr	About to apply for NDA. Will spend about \$10	i.5	4
	Fox	Columbia U.	Silver Sulfadiazine used in Treatment of Burns	Marion Labs., Kansas City, Mo.	Now on market - Approx. \$5,000,000	2.0	7
v (15.1)	Heidelberger	U. of Wisconsin	Use of F ₃ TOR for Herpes Infections of the Eye	Burroughs Wellcome Co., Research Triangle Park, N.C.	Approx. \$5,000,000 NDA expected by end of 1977.	2.0	6
gan.	Fischell	Johns Hopkins U.	Rechargeable Cardiac Pacemaker		On market since Feb. 1975 - Approx. \$720,000	2-1	8
	Holland	Tulane U.	Method of Reducing Intra- ocular Pressure in the Human Eyes (Glaucoma Treatment)		\$2,000,000 - Development leading to DNA is in process and on schedule	2.4 -	5
	Pressman	U. of Miami	Application of X-537A in the Cardiovascular Syste (for stimulation in card genic shock, congestive heart failure, etc.)	n Nutley, N.J.	Clinical evaluations still in progress	2.0	3
- 8-8 (175)	Higley .	Natl.:Institute of Scientific Research	Polycarbonate Dialysis Membranes (kidney dialysis)	C. R. Bard Inc., Murray Hill, N.J.	Over \$1,000,000. Market introduction expected imminently.	3 2.2	4
	Talbot/Harrison	Johns Hopkins U.	Ballistocardiograph Apparatus	Royal Medical Corp. Huntsville, Ala.	Approx. \$330,000. Now on market.	1.0	est operation 6 value

	SAMPLIN	G OF UNIVERSITY PATENT LICEN	-3-	an a marang an ay war itan a gasan a marang an ay war itan	* GREAT, MODE	RATE, MINIMAL, INNE
Inventor	University	Invention	Licensee	Approximate Investment	Yalue*	O pineins"
Plotkin	Wistar Institute	E Santonia Santonia	Foundation 2) L'Institut	Approx. millions - Now on market.	3.0	8
	to the way the		Vaccine Institu	te and others (Angelia is an firm, etc.)	\\ \\\^2\\\	
Schaffner/Hechlins	ki Rutgers U.	Derivatives of Polyene Macrolide Antibiotics	E.R. Squibb of U. S. A.	Millions - Clinical trials progressing favorably	2.0	4
	A STATE OF THE STA		and Dumex of Denmark			pers
Zweig	Syracuse U.	Apparatus for Measuring and Controlling Cell Population Density in a Liquid Medium	New Brunswick Scientific Co., Inc., of New Jersy	Millions - On the market since 1973	1.2	4
Lovelock	Yale V. A. Jakistan	Gas Analysis Method	Palo Alto Calif	and the second s	2.2	4
e Co	· · · · · · · · · · · · · · · · · · ·	Qualitative and Quantitative Analysis of Classes of Organic Vapors			2/2	
Fried	U. of Chicago	Prostoglandins for possibl Treatment of Bronchial	Merrell, New York	Several millions - In process of development	2.4	7
, communication		Asthma, Duodenal Ulcers, Inflammatory Conditions, e		and testing for marketing here and abroad	2 1 2 1 Mari	77.3
Leininger/Grotta et al	Battelle Memorial Institute	Preparation of Non- thrombogenic Surfaces and Materials	C. R. Bard, Inc., Billerica, Mass.; Sherwood Medical Industries, St. Lo	\$107,754 - Some products being marketed and others being tested.	√ j. 8	n Sa r (1987) Marka Bar
•		F 4 1	Mo.; and American Hospital Supply Co	**	and the second	and the second

Irvine, California:

		grant da.			OREAL PODERAIE	MINIMAL, INONE
Inventor	University	OF UNIVERSITY PATENT LICENSI Invention	NG PROGRAMS	Approximate Investment	, Ç Va1µe*	Opinions-
Inventor	University	invention	Licensee	Approximate Thes Dient	value*	7Op1ov.3
Herrifield	Rockefeller U.	Apparatus for the Automated Synthesis of Peptides		Being marketed since 1973.	2,0	5
Smith/Kozoman -	Duke U. (1999) est	Apparatus and Method		\$25,000 - Being marketed	1.4	i i
· · · · · · · · · · · · · · · · · · ·	e Navideti	for Rapid Harvesting of Roller Culture Supernatant Fluid	Vineland, New Jersey	since June 9, 1976) a	, sį
Zweng	Stanford U.	Laser Photocoagulator	Coherent Radiation, Palo Alto, Cal.	Approximately \$500,000 Standard tool of ophtholmologists	2.3	8
Sweet et al	Stanford U	Cell Sorter	8ecton-Dickinson, Rutherford, New Jersey	Approx. \$200,000. Import research tool	tant = 1.5	4
Boyd/Macovski	Stanford U.	Computerized Axial Tomography	S.A.I. Cupertino, Cal.	Approx. \$300,000. Will be marketed soon.	2.7	7
Saxena (4) 3	Cornell U.	Method for Testing for Pregnancy	Carter-Wallace	Approx. 1/2 million On market	2.6	6
Calnek/Hitchner	Cornell U.	Cell-free virus. Preparation	Merck	turnor i kritorio e	[[]] 2.2	984 4 8
Carlson	Iowa State	Respiratory Augmentor with Electronic Monitor and Control	Sourns, Inc.	On market since 1966; sales now in millions	,2.l	6
Leake/Rappoport	Harbor General Hospital	Bone Induction in an Alloplastic Tray	Am. Hospital Supply	Data not available	. · · · · · · · · · · · · · · · · · · ·	

er en	STORY SERVICE COMPLETE	S OF UNIVERSITY PATENT LICENSIN	-5-	Tempor Transcriptor Mayerbard Co. To the Common American Co.	* GREAT, MODERATE	, Minimal, Ikre
Inventor	University	Invention	Licensee	State of Development	Value*	Opinions.
Bradford/	U. of Georgia	Protein Assay Reagent and Method: 1949	Bio-Rad Labs, Inc; Quantimetrix Corp.	On the market since April 1977	1.4	4.
Tenckhoff	U. of Washington	Catheter Insertion Trocar	Sweden Freezer Mfg. Co: Cobe Labs: Physio-Control Cor	On market	1.2	5
Jan Leonard et al	U. of Illinois	Fluorescent Derivatives of Cytosine-Containing Compounds	PL Biochemicals	On market vije stopinski se Charan prosestinski	sec. 1.0 5	L.:
Secrist et al	U. of Illinois	Fluorescent Derivatives of Adenine-Containing Compounds	PL Biochemicals	On market	1.05	L.
Asgar	U. of Michigan	Partial Denture Alloy	ģeur Σ [*] . Attojina	On market	1.5	4
Carlson/Ward	U. of Washington	Coherent Biological Cell Analyzer	3M Company	Marketing development in progress.	1.6	<i>3</i>
Charlson/ Alhquist	U, of Washington	Integrating Nephelometer and Photon-Counting Integrating	Battelle Develop- ment	On market	2.0	3
Milko ,	£v;T\$44;Ba	Nephelometer	1 / Eyari	grande, in the take which	William .	y single
Thomas	U, of Washington	Artery-Vein Shunt Applique	Battelle Develop- ment Corp.	Being marketed	1.6 -, 6.5% - 5.6% II	う (17) (1881年 - 17)

SAMPLING OF UNIVERSITY PATENT LICENSING PROGRAMS

	Inventor	University	Invention	Licensee	State of Development	Value*		Deinions
. 121. . 65	Holcomb	Yale University	Method and Apparatus for Stimulation of Body Tissue	Avery Labs, Inc.	On the market since 197	1.5		2.
	Dugan,	Temple University	Novel Compositions for Radiotracer Localization of Deep Vein Thrombi	Rand Research & Development Corp.	Cicensed in 1977.	1.2	#1.74 - 1.15	5
	Roelofs	Cornell University	Codling Moth Pheromone	Zoecon Corp.	On market since 1972.	2.0	Market Comments	Ę
	Whitby	Univ. of Minnesota	Particle Counter	Name not available	On market since 1969	1.5	6.55	2
51.	Backaner	Univ. of Minnesota	Method for Suppressing Ventricular Fibrillation	Burroughs Wellcome	ABout to be marketed	2.6		5
2	Whitby	Univ. of Minnesota	Aerosol Sampler	Not available	On market since 1969	1.0		
	Eradley	Univ. of Minnesota	Apparatus to Stimulate the Bladder	Two licenses, names not available	On market since 1972	1.77	Alexander (5
	81ackshear	Univ. of Minnesota	Implantable Infusion Pump	Metal Bellows Company	About to be marketed	2.5	jeny jedi	8
	Lillehei	Univ. of Minnesota	Pivoting Disc Heart Valve	Name not available	On market world-wide since 1971	1.7	900 200 200 200	4
•	Butler	Purdue Research Fdm.	Hydrophobic Moncovalent Binding of Proteins to Support Materials	Regis Chemical	On market since April 1	-	e line	
		4.9.			를		800	1 % 1 %
٠	Rosenberg	Michigan State Univ.	Platinum Compounds as Anti-Turmor Agents	Possibly Adria, Bristol or Milés Labs.	On market in late 1977	2.5		5
*	Coller	Institute for Cancer Research	Process of Viral Diagnosis and Reagent (Radioimmuno- assay)	Abbot Labs.	Licensed in 1977 (Canada)	2.2		5

IN THE

Supreme Court of the United States

OCTOBER TERM, 1977

No. 77-922

CHRYSLER CORPORATION, Petitioner

V

HAROLD BROWN, et al., Respondents

On Writ of Certiorari to the Court of Appeals for the Third Circuit

BRIEF AMICUS CURIAE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

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CHRYSLER CORPORATION, Petitioner

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HAROLD BROWN, et al., Respondents

On Writ of Certiorari to the Court of Appeals for the Third Circuit

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BRIEF AMICUS CURIAE ASSOCIATION OF AMERICAN MEDICAL COLLEGES

OPINIONS BELOW

The opinion of the court of appeals is reprinted as Appendix A to the Petition for a Writ of Certiorari. The opinion of the district court is reported at 412 F. Supp. 171.

JURISDICTION

The jurisdiction of this Court rests on 28 U.S.C. § 1254 (1).

CONSENT TO FILE*

This Amicus Curiae brief is being filed with the consent of all the parties to the proceeding.

^{*} Letters of consent of all parties to the case have been filed with the Clerk of the Court.

INTEREST OF AMICUS

The Association of American Medical Colleges is a voluntary, nonprofit, non-governmental corporation established under the laws of the State of Illinois, having its principal place of business in the District of Columbia. Its corporate purpose is the advancement of medical education. Its institutional membership includes all one hundred twenty one accredited and operating nonprofit medical schools and medical colleges in the United States. Its membership also includes over 400 teaching hospitals in which undergraduate and graduate medical education is conducted, and 63 academic and professional societies, the members of which are actively engaged in medical education and the conduct of biomedical research.

The members of the Association of American Medical Colleges (AAMC) conduct a substantial proportion of the nation's Federally supported biomedical research. Health related research and development is in large measure supported by the Federal Government; it provided nearly \$2.8 billion for this purpose in 1975 out of a total national investment of more than \$4.6 billion. Of this, \$1.74 billion was expended in institutions of higher education. The National Institutes of Health, chief sponsor of medical research and development awarded \$1.07 billion in Federal research grants and contracts to institutions of higher education of which \$808 million was awarded to medical school members of the Association of American Medical Colleges and an additional \$24.5 million to member hospitals.1

¹ Figures taken from Tables 2 and 21, Basic Data Relating to the National Institutes of Health, DHEW Publication No. (NIH) 77-1261, 1977.

Thus the institutions represented by amicus have a major role in the nation's system for conducting Federally sponsored research. Its interest in this case stems from the impact of the operation of the Freedom of Information Act (FOIA)² and the Federal Advisory Committee Act (FACA)³ on that system. Amicus believes that a measure of confidentiality is a necessary feature of governmental review, evaluation and handling of research grant applications. Protection from premature disclosure of an investigator's ideas is necessary to assure that the full fruits of government funded research are available to the public and are essential to the preservation of important intellectual property rights.

QUESTIONS PRESENTED A COMMON COMPON COMMON COMPON COMPON COMPON COMPON COMPON COMPON COMPON C

The questions before the Court include whether Exemption 4 of the FOIA is permissive or mandatory; whether agency regulations promulgated pursuant to 5 U.S.C. § 301 constitute "authorization by law" within the meaning of 18 U.S.C. § 1905 for disclosure of private, confidential business information; whether a submitter of information is limited to judicial review of the agency record as his only recourse in the event of an agency determination adverse to interests he asserts are protected by Exemption 4 and/or 18 U.S.C. § 1905.

Reformulated in terms reflecting the perspective of amicus, the fundamental question is: May the Federal government, as possessor of valuable information as a

² 81 Stat. 54, 5 U.S.C. § 552 (P.L. 90-23, 90th Congress, 1st Session (1967), as amended).

³ 86 Stat. 770 (P.L. 92-463, 92nd Congress, 2nd Session (1972), as amended).

consequence of its offer to support research projects it deems to be in the public interest, at its discretion, effect a diminution of the value of the ideas to submitting investigators, foreclose the transformation of the ideas into commercially valuable intellectual property, and deprive the public of potential benefits from Federally funded research?

Amicus recognizes that the specific items of information giving rise to this case are conceded by the parties to fall within the scope and coverage of Exemption 4. Accordingly, it recognizes that arguments as to the merits of including information contained in EEOC reports, affirmative action plans and the like within the scope of Exemption 4 are not pertinent to this case. Amicus will, however, direct some discussion to issues related to the scope of Exemption 4 in order to illustrate to the Court the injury to the public interest that will result from any determination that the exemption is discretionary rather than mandatory.

SUMMARY OF THE ARGUMENT

Creative ideas are valuable to a research investigator as his stock-in-trade and to society as a means of facilitating solutions to important national problems. To the extent that it may result in product innovations, an investigator's work is both of commercial significance and of public benefit in making available useful materials, such as, for example, life saving drugs or medical devices. Preservation of these values, however, requires that the investigator's ideas and works not be given premature public disclosure.

The FOIA and the FACA affect the timing of disclosure and should be interpreted in a fashion to protect both the investigator's and the public interest. Such an interpretation is consistent with sound public policy, with Congressional intent, and with Constitutional directives.

ARGUMENT

I. An Investigator's Ideas and Creative Work Are Valuable

A. TO THE INVESTIGATOR BECAUSE:

The advancement, remuneration, professional recognition, and personal satisfaction of a scientist depend upon the soundness of his ideas and the skill with which the scientist applies them to a research problem. The problems selected by applicants in seeking Federal research support and the results of the research (in terms of contribution to science, recognition of the effort as an original product, being the first to publish the research findings, and the like) are thus of substantial "proprietary" interest to him and are traditionally treated in this regard by the scientific community and by the Federal granting authorities, regardless of the locus of research.

- B. To society at large for their contribution to the resolution of problems of public significance because:
- 1. They illuminate our understanding of human problems. Federal agencies support academic research

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One member of an NIH initial review group (Dr. Walter Eckhart of the Salk Institute) characterized the importance of an application to an applicant as follows: the 4 to 5 hours a primary reviewer may spend studying an application "is done not so much because of a sense of responsibility or what the other members may think of your presentation, but because one knows that for the applicant it's a matter of life or death". Quoted in Wade, "Peer Review System: How to Hand Out Money Fairly", 179 Science (No. 4069) 158, 159 (1973).

because of public recognition of the contributions such research may make to the solution of human problems. For example, the Department of Health, Education, and Welfare is authorized to "encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and [to] promote the coordination of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control and prevention of physical and mental diseases and impairments of man . . . " 42 U.S.C. § 241. Specifically, the Department of Health, Education, and Welfare is authorized to make "grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects." 42 U.S.C. § 241 (c).

The recognized preeminence of the United States in the field of biomedical research, the scientific capabilities of modern medicine, the advances made in alleviating or ameliorating previously devastating disease problems testify to the success of this approach. The continual increase in appropriations for the programs of the National Institutes of Health, testify to the Congressional and public support of this as an appropriate public policy.

2. They are a source of innovations resulting in useful products.

"From 1969 through the fall of 1974 estimates of the Department show that the intellectual property rights to 329 innovations either generated, en-

⁵ NIH appropriations have increased from \$34.8 million in 1950 to over \$2.5 billion in 1977. Basic Data Relating to the National Institutes of Health, DHEW Publication No. (NIH) 77-1261, 1977, Table 12.

hanced, or corroborated in the performance of Department [of Health Education and Welfare]—funded research were under control of university patent-management offices ..."

These innovations included drugs and therapeutic agents which promise great benefit in improving health and improving the quality of life of mankind.

II. An Investigator's Ideas, Properly Developed, Often Are Transformed Into Commercially Valuable Property.

It is clear from the preceding quotation that an investigator's ideas and research efforts often result in patentable innovations. It should also be apparent that when this work has matured from a concept to a patented innovation it is transformed into identifiable "intellectual property" and its owner acquires substantial protection under U.S. patent and property laws. Furthermore, an idea or innovation may be commercially valuable, even absent the protections of a patent, if it is managed in a manner suitable to acquiring and preserving the character of a trade secret.

Patented innovations are of little direct concern in this case because of their protection in law. Of direct and substantial concern to amicus, however, are those inchoate forms of intellectual property represented by an innovation which may be patentable, but is not yet at a stage where it can be patented, and those insights which may form the basis for a commercially valuable trade secret. The possibility of obtaining a patent is jeopardized and, in some cases foreclosed, by uncondi-

Report of the President's Biomedical Research Panel—Disclosure of Research Information, at 15. DHEW Publication No. (OS) 76-513, June 30, 1976.

tioned disclosure prior to the filing of the patent application. A trade secret loses its value upon disclosure to the public.

Patent laws of both the United States and foreign countries are drafted against the interest of those parties making or permitting publication of their innovation prior to the filing of a patent application. In the United States, publication of an unpatented invention initiates a one-year statutory period for filing a patent application on the innovation or valid patent protection is precluded. In most foreign countries valid protection is precluded if a patent application had not been filed *prior* to the date on which the information was *first* disclosed.

Within the patent laws, publication has been broadly defined as any unconditional disclosure by its owner of information on an innovation of interest. For example, even a thesis available on the shelves of a university library but not necessarily reviewed by any researcher has been deemed in the context of the patent laws, to be a publication of the innovation disclosed therein.

- III. Exemption 4 of the FOIA is of Crucial Significance in the Protection of an Investigator's Ideas.
- A. PREMATURE DISCLOSURE DIMINISHES AN INVESTIGATOR'S STOCK-IN-TRADE.

Traditionally, Federal granting agencies have recognized and protected a scientist's proprietary inter-

⁷ Hamilton Laboratories v. Massengill, 111 F. 2d 584, 45 U.S.P.Q. 594 (6th Cir. 1940); Indiana General Corp. v. Lockheed Aircraft Corp., 249 F. Supp. 809, 148 U.S.P.Q. 312 (S.D. Cal. 1966); Gulliksen v. Halberg, 75 U.S.P.Q. 252 (Bd. App. 1937); Ex parte Hershberger, 96 U.S.P.Q. 54 (Bd. App. 1952).

est in his work. Applications submitted for funding and the research protocols they contained have been withheld from disclosure under the authority of Exemption 4. It was clearly recognized that making the preliminary research, research designs and protocols public at the time of application would violate the proprietary rights of applicants and greatly enhance the danger that the applicant's ideas (his stock-in-trade) will be appropriated by others. Another researcher might modify the original proposal, be awarded the grant and be the first to publish findings thereby not only causing loss of the research opportunity and grant to the initial applicant but also crediting the subsequent applicant with the idea.

These concerns of the research scientist are very real and highly important, and preoccupy them constantly. The essence of this concern was expressed by Dr. James Dewey Watson, Nobel laureate and Professor of Molecular Biology, Harvard University, when he candidly said that "we [scientists] all know too well that the types of jobs we eventually get are very much dependent upon how much we produce. There is little enthusiasm for those who always come in second." Professor Watson, in observing that "success in generating new ideas usually being more than the simple combination of native intelligence and a good measure of luck", pointed out that "(a)ll too often science resembles playing poker for very high stakes, where re-

⁸ Watson, "The Sharing of Unpublished Information," second Frank Nelson Doubleday Lecture for 1973-74, at the National Museum of History and Technology, January 29, 1974, prepared remarks at 4.

vealing one's hands prematurely makes sense only when you have all the low cards."

This policy of governmental protection of a scientist's ideas was challenged by the Washington Research Project, Inc. when denied access to research protocols funded by the National Institutes of Mental Health. The court concluded, in denying the use of the "trade secrets" exemption, that

"It is clear enough that a noncommercial scientist's research design is not literally a trade secret or item of commercial information, for it defies common sense to pretend that the scientist is engaged in trade or commerce. This is not to say that the scientist may not have a preference for or an interest in nondisclosure of this research design, only that it is not of trade or commercial interest..." 11

While the court allowed, in a footnote, that it might have reached a different result had there been a demonstration of the commercial character of the research projects at issue, *amicus* contends that this overly narrow reading of Exemption 4 focuses unduly on the nature and organizational locus of the submitter rath-

⁹ Id. at 3.

¹⁰ Washington Research Project, Inc. v. Weinberger, 504 F.2d 238 (D.C. Cir. 1974), cert. denied, 421 U.S. 963 (1975).

ontention, did not take cognizance of the very extensive activities of many colleges and universities in licensing their inventions for commercial development. For example, the [University] of Wisconsin Alumni Research Foundation has, over a 51 year period, licensed inventions resulting in nearly \$2 billion in sales and the return of substantial royalties utilized for university research. Hearings on the Business Record Exemption of the Freedom of Information Act before a Subcommittee of the House Committee on Government Operations, 95th Cong., 1st Sess. (1977), at 321.

er than the character of the information and the interests at stake. Certainly an argument can be made that protection, under law, of the intellectual property of investigators employed at universities and other nonprofit institutions ought to be equal to that protection accorded commercial firms. If Exemption 4 were considered to cover the information protectable under 18 U.S.C. § 1905, it seems clear that universities and nonprofit organizations would as a minimum occupy a position equal to commercial concerns under FOIA and FACA, since the protection anticipated by 18 U.S.C. § 1905 clearly extends to non-commercial organizations as well as to commercial enterprises. Further, such an approach would assure more predictable protection because 18 U.S.C. § 1905 contains a definitive identification of proprietary information and because Government officials would carefully adhere to this definition due to the penalties prescribed.

In the view of Representative John E. Moss, known as the "Father of FOIA," it was the Congressional intent that there be a close identification of 18 U.S.C. § 1905 and Exemption 4. In a summary of a November 10, 1975, meeting on FOIA with Representative Barry Goldwater, Jr.,:

"Mr. Moss indicated that, as an original author of the Freedom of Information Act, it was his intent and understanding that exemption (b) (4) would authorize the withholding from disclosure under that Act of all 'confidential information' protected by 18 U.S.C. 1905 in the criminal code. He further indicated that 18 U.S.C. 1905 was not intended as the authority to withhold such information under the Freedom of Information Act, but rather it was to be the test for what information was authorized to be withheld under the authority in exemp-

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tion (b) (4). He expressed disappointment that recent court holdings have not correctly interpreted this connection and often have held to the contrary that 18 U.S.C. 1905 information is not necessarily protected under (b) (4), based on the adoption by the courts of various other tests for exemption (b) (4) coverage." ¹²

B. PREMATURE DISCLOSURE DESTROYS THE TRADE SECRET VALUE AND POTENTIAL PATENTABILITY OF INNOVATIONS.

Notwithstanding the decision in Washington Research Project, and assuming arguendo that it correctly states the law with respect to funded applications where no specific showing of a commercial interest is made, there remains a basic and difficult problem regarding the treatment of inchoate intellectual property resulting from judicial interpretations of Exemption 4 and the administrative difficulties of agency compliance.

To the extent that FOIA requires disclosure prior to the funding of research projects, it is unrealistic to expect that investigators or their institutions would be able to protect their intellectual property rights by filing a patent application at this early stage of investigation. The clinical or other corroborating data necessary to support a patent claim would obviously be lacking. The filing of a patent application without such data, if possible at all, would be based on the uneconomic, speculative basis of possible future findings. The unfunded investigator with a research proposal before the Government would be foreclosed from

¹² 121 Cong. Rec. H 12379 (Dec. 11, 1975). The full Summary of the Nov. 10, 1975, meeting is attached as Appendix A.

the protection of his innovative ideas as trade secrets under the common law to the extent that disclosure is required under FOIA.¹³

FOIA would appear to require that unfunded research proposals be reviewed on an individual case basis as to whether they are exempt from disclosure under Exemption 4. However, it is difficult (if not impossible) to determine at the design phase of an experiment whether and to what extent it is exempt from disclosure under this authority. As to those portions that might be deemed exempt under Exemption 4, at that stage it is even more difficult to segregate data of potential commercial significance from those that do not have this value. In fact, the experiment itself, if funded, is conducted to answer these questions. This administrative quagmire demonstrates the practical difficulty of providing adequate protection for unfunded research proposals under the FOIA.

This difficulty is compounded by court interpretations of Exemption 4. The decision from the leading case on this exemption (National Parks and Conservation Association v. Morton, 498 F. 2d 765 (D.C. Cir. 1974)) states that the exemption applies if it can be shown that disclosure was likely either, first, to impair the Government's ability to obtain necessary infor-

is In other circumstances, an application for governmental assistance does not constitute a waiver of an innovator's claim to protection from disclosure of a trade secret. See, e.g., Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470 (1970) (the enactment of the U.S. patent laws do not deprive States of their ability to protect trade secrets); Sears v. Gottschalk, 357 F. Supp. 1327 (E.D. Va. 1973), aff'd. 502 F. 2d. 122 (4th Cir. 1974) (patent applications denied patent protection are nevertheless protected from disclosure under the FOIA by Exemption 4 as trade secrets).

mation, or second, to cause substantial harm to a competitive position of a person providing the information. The standard was further restricted in *Petkas v. Staats* (501 F. 2d 887 (1974)) where the court refused to accept a Government assurance of nondisclosure contained in a regulation requiring information. A corporation's reliance on this assurance, and the filing of the information conditioned on confidentiality, were not considered determinative and the court remanded the case for disposition in accordance with the test of the *National Parks* case noted above. Consequently, a pledge of confidentiality by the Government, in and of itself, may not prevent disclosure.

Further, Title 18 U.S.C. § 1905 appears to be given little effect in Freedom of Information Act suits. This statute, when applicable, imposes criminal penalties on Government officials who disclose proprietary information in the possession of the Government. It is a deterrent to unauthorized disclosure, although it takes effect only after the disclosure and the damage has been suffered by the owner. Title 18 U.S.C. § 1905 contains a general exemption, "unless otherwise provided by law", and has not been given effect by some courts in Freedom of Information Act suits. These courts have interpreted the quoted passage as permitting disclosure under the Freedom of Information Act, or as the court below, under agency disclosure regulations. The penalties specified in Section 1905, therefore, have not been applied to an official who disclosed proprietary information in response to a Freedom of Information request.

Since the Government controls the preponderance of the financial resources now supporting research at universities and non-profit organizations, especially in the area of biomedical research, it is clear in practice that a university or nonprofit organization investigator seeking. Federal support to verify his innovative ideas will not be able to protect his inchoate or identified intellectual property under the first test of National Parks (impairment of government's ability to obtain material). If susceptability to disclosure is a condition of seeking Federal funding, investigators will not be in a position to refuse to submit their research proposals for funding because of the financial leverage possessed by the Government.

Even though commercial concerns might, with some difficulty, meet the second or "substantial harm to a competitive position" test of the National Parks case, universities and nonprofit organizations wishing to control access to their unfunded research proposals appear to have an even greater burden in meeting this test in light of Washington Research Project, Inc."

C. THE WITHHOLDING OF A RESEARCH PROPOSAL IS IN-ADEQUATELY PROVIDED FOR UNDER PRESENT CASES COVERING THE FOURTH EXEMPTION OF FOIA.

In order to deny information, the Federal administrator handling the request must apply the National Parks test to the situation and provide to the Department Public Information Officer a written prima facie case for denial. (The case would need to include arguments on how a nonprofit organization could have a competitive position in order to overcome the negation of such possibility by the National Parks and Washington Research Project, Inc., cases.) Before a prima facie case could be made to deny a disclosure request involving an idea, invention, or discovery, a prior art

review would need to be conducted indicating that such an idea, invention, or discovery is in fact novel in comparison to the "prior art". If novelty cannot be shown, it seems clear that the Government could not prevail in a suit to show that there will be "substantial harm to the owner's competitive position." It is worth asking whether a Federal administrator, even with the aid of the investigator whose idea is involved, can show, especially prior to the funding of a research proposal, that such proposal is novel compared to the prior art. The primary purpose of conducting the research is to demonstrate that the idea is indeed novel

Even if the Federal administrator is able to make a prima facie case establishing that the research proposal falls within the fourth exemption, there is no guarantee that the Department Public Information Officer would accede to the recommended denial in light of the May 5, 1977, instructions from the Attorney General to the Agencies of the Executive Branch that

"The government should not withhold documents unless it is important to the public interest to do so, even if there is some arguable legal basis for the withholding. In order to implement this view, the Justice Department will defend Freedom of Information Act suits only when disclosure is demonstrably harmful, even if the documents technically fall within the exemptions in the Act." ¹⁵

The need to adequately protect these inchoate or identifiable rights prior to Government funding becomes more apparent when it is realized that only

¹⁵ Letter to Heads of all Federal Departments and Agencies re: "Freedom of Information Act" dated May 5, 1977, from Griffin B. Bell, Attorney General, copy attached as Appendix B.

approximately one-third of these proposals are in fact ultimately funded. Thus, if disclosure of these proposals on receipt by the Government becomes the rule rather than an exception, the intellectual property in the two-thirds of unfunded proposals will be forever destroyed without an offsetting benefit to the submitting investigator or the public. Amicus believes adequate safeguards for the protection of intellectual property rights of investigators with research proposals before the Federal Government is a matter of basic equity and sound policy. Protection of intellectual property is a right recognized by the Congress and the courts in implementing Article I, Section 8, Paragraph 8 of the Constitution and the common law protection afforded those who wish to maintain their innovative ideas as secrets. Moreover, the remarkably productive partnership between the Federal Government and the non-Federal research community is based in part on the principle of protection of the ideas of such investigators and is widely considered to be in the best interests of the American people. tendetoh tendetek berilikari enleroto

IV. Harm to the Public Interest Results from Current Unpredictability of Protection from Disclosure.

Amicus believes it is possible to estimate, in a general sense, the potential harm that results if protection of individual intellectual property by Government agencies remains in its present state of unpredictability. Amicus has long been concerned with the problems of transfer of research progress, technology, and information from the "laboratory bench to the public."

A number of studies have yielded evidence of a clear link between the need to protect intellectual property rights and the successful transfer of research innovations to the delivery of health care. In a 1968 report, "Problem Areas Affecting Usefulness of Results of Government-Sponsored Research in Medicinal Chemistry," the General Accounting Office pointed out that from 1962 to 1968 there was a virtual industry-wide boycott on the exploitation of drug research leads generated by research sponsored by the National Institutes of Health. This report forcefully concludes that where substantial private risk investment is needed, such as that required for premarket clearance of potential therapeutic agents and, now, of some classes of medical devices, there is an identified likelihood that transfer will not occur if the entrepreneur is not afforded some property protection in the innovation offered for development.

Since 1968 there have been specific efforts through the patent program of the Department of Health, Education, and Welfare to close the recognized gap between the discoveries made under research support and the willingness of private industrial developers to invest the funds necessary to deliver the innovations to the market place. The main thrust of the Department's patent policy has been to assure that the innovating group has the right to convey whatever intellectual property rights are necessary for possible licensing of industrial developers. Not all transfers of potentially marketable innovations from such organizations require an exchange of intellectual property rights in the innovation, but it is unpredictable in which transfers entrepreneurs will demand an exchange to guarantee their collaborative aid.

¹⁶ GAO Report No. B-164031 (2), 1968.

"During the period from 1969-1974, 44 nonexclusive and 78 exclusive licenses had been negotiated under the patent applications filed through these university patent-management offices. According to the figures furnished by the Department, the 122 licenses negotiated have generated investments of around \$100 million of private risk capital, in complete contrast to the period 1962 to 1968, during which there was almost no industry interest in research leads of Department-funded research. In the period 1969 to 1974, two licenses resulted in the marketing of two drugs, while a number of other licenses cover potential therapeutic agents in various stages of pre-market clearance. This record is even more impressive in view of the fairly lengthy period required to obtain approval to market a new drug." " seen rescrib vell seed of

In the above context, it is apparent that the existence of a licensable patent right may be a primary factor in the successful transfer of a university innovation to industry and the marketplace. Amicus is concerned that the failure to protect and define such rights may fatally affect the transfer of major health innovations.

For this reason, amicus is seriously concerned about the unpredictability of Government protection for intellectual property rights, because of the uncontrolled and unconditioned disclosure of research information under current court interpretation of FOIA. This state of affairs is likely to stifle industry interest in developing potentially important research innovations. Without industry involvement, the transfer of research findings to clinical practice will be impeded.

¹⁷ Report of the President's Biomedical Research Panel, supra note 6 at 15.

In the judgment of amicus, there are strong reasons to conclude that the interface between research and health care delivery, an area of vital national interest, is likely to be impaired unless adequate protection is provided for intellectual property rights of investigators whose research is conducted with Federal financial support.

V. The FOIA Must Be Interpreted Consistent With Relevant Constitutional and Statutory Provisions and with the Public Interest.

The Freedom of Information Act contains no provision for according submitters of information due process of law in any decision to disclose information of value to the submitters. Nor does the Act contain a provision to compensate the submitter for the value of information destroyed by its disclosure to the public. As asserted above, the result of disclosure is a general harm to the long range public interest. These considerations argue forcefully that the Congress never intended a submitter of information to be disposessed of valuable property by operation of the FOIA. Instead, Congress intended, as stated by Mr. Moss, that Exemption 4 would preserve the confidentiality of such valuable information and that it would be read in conjunction with Section 1905 of Title 18. A contrary reading of Exemption 4 has the effect of subverting the Constitutional mandate that Congress promote the useful arts, Article I, Section 8, Paragraph 8, and would be violative of the clear mandate of the Fifth Amendment of the Constitution prohibiting the deprivation of property without due process of law. These considerations in turn lead to the conclusion that Exemption 4 constitutes a mandatory prohibition against the disclosure by government agencies of information described therein and in Section 1905 of Title 18.

CONCLUSION TO THE PARTY OF THE

It is the position of amicus that the public interest is served by a governmental policy which accords adequate recognition to the concept that the research investigator's ideas are valuable and constitute actual or inchoate intellectual property. Untimely disclosure or unrestricted access to materials contained in research grant applications through the operation of the FOIA will result in the destruction of valuable property rights, will undermine the effectiveness of the system for awarding grants on the basis of scientific merit, and will inhibit and in some cases preclude the transfer of technology from the "laboratory to the patient bed." These conclusions are supported by and reflected in the recommendations of two independent Congressionally commissioned studies of the implication of disclosure of information contained in research protocols. research hypotheses, and research designs obtained by the Secretary of Health Education and Welfare in connection with applications or proposals submitted to the Secretary for a grant, fellowship, or contract under the Public Health Service Act. 18

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¹⁸ Report of the President's Biomedical Research Panel—Disclosure of Research Information, DHEW Publication No. (OS) 76-513, June 30, 1976.

Disclosure of Research Information under the Freedom of Information Act—The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, DHEW Publication No. (OS) 77-003, 1977.

While each of these reports conclude that new legislation will be required to assure these objectives, amicus contends that they will be achieved through a proper construction of Exemption 4 of the FOIA and 18 U.S.C. § 1905, by this Court.

- 1. Consequently, we conclude and urge this Court to hold that Exemption 4 of the FOIA must be interpreted as a mandatory prohibition of agency action to disclose information described therein or in Section 1905 of Title 18.
- 2. Amicus strongly supports petitioner's contention that 5 U.S.C. § 301 does not constitute authorization by law within 18 U.S.C. § 1905 for disclosure of private, confidential business information. This conclusion, is essential to prevent the evisceration of Exemption 4. Finally it is consistent with sound public policy to provide protection to information submitted to the Government by universities and nonprofit organizations on an equal footing with information submitted by commercial concerns.
- 3. Amicus further supports the petitioner's contention that persons supplying information believed to fall within the Exemption or the protection of 18 U.S.C. § 1905 are entitled to a trial de novo prior to disclosure of such information by the Government. Amicus believes that the Government's unilateral ability to release privately owned intellectual property, inchoate or identifiably patentable subject matter, or information protectable at common law as secret, is constitutionally suspect as a disposition of property without due process of law and thus requires adequate opportunity for the submitter to enjoin such release before irreparable damage occurs.

For the foregoing reasons, the decision of the circuit court should be reversed. To a confidence of the circuit

Respectfully submitted,

JOSEPH A. KEYES, JR.

Attorney for Amicus Curiae
Suite 200. One Dupont Circle, N.W.
Washington, D.C. 20036

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Summary of Meeting of Representative John E. Moss with Representative Barry M. Goldwater, Jr., on the Freedom of Information Act, Nov. 10, 1975

- 1. We agreed that it is extremely important and in the national interest that ERDA have the full cooperation and participation of the private sector, particularly American industry, in the conduct of the national energy R&D effort. This cooperation and participation is essential to ensure the success of the national effort, by providing ERDA access to existing technology and access to past, present and future successes and failures in the private sector's energy R&D activities in order to most effectively manage a visi iznolica e... the national effort.
- 2. We agreed that any lack of predictable protection of the private sector's proprietary information under the existing Freedom of Information Act exemption from mandatory disclosure for such information (5 U.S.C. 552(b) (4)) could seriously inhibit private sector cooperation and participation with ERDA to the detriment of the national energy research and demonstration program.
- 3. Mr. Moss acknowledged Mr. Goldwater's conclusion, based on an independent staff legal analysis, that protection under exemption (b) (4) is neither predictable nor adequate because of recent court interpretations of the exemption. noticineza (2014) a sia
- 4. Mr. Moss indicated that, as an original author of the Freedom of Information Act, it was his intent and understanding that exemption (b) (4) would authorize the withholding from disclosure under that Act of all "confidential information" protected by 18 U.S.C. 1905 in the criminal code. He further indicated that 18 U.S.C. 1905 was not intended as the authority to withhold such information

under the Freedom of Information Act, but rather it was to be the test for what information was authorized to be withheld under the authority in exemption (b)(4). He expressed disappointment that recent court holdings have not correctly interpreted this connection and often have held to the contrary that 18 U.S.C. 1905 information is not necessarily protected under (b)(4), based on the adoption by the courts of various other tests for exemption (b)(4) coverage.

- 5. Mr. Moss indicated that exemption (b)(3), "specifically exempted from disclosure by statute" could be utilized to create a narrow statutory exemption in other statutes where Congress concluded that there was a legitimate national interest to be effectuated by withholding a class of information. In so concluding, Congress must strike a reasonable and acceptable balance between that national interest and the national interest in public access to Federal government information effectuated by the Freedom of Information Act.
- 6. We agreed that, in light of the apparent state of unpredictability of protection for proprietary information under exemption (b) (4) and the need for ERDA to provide such predictable protection in order to ensure the full cooperation and participation of the private sector, Congress could conclude that there was a legitimate national interest in ERDA's having the specific authority to predictably protect proprietary information. Further, Congress could strike a reasonable and acceptable balance of that national interest and the national interest in freedom of information and create a (b) (3) exemption for ERDA for that purpose.
- 7. Finally, we reviewed a draft of a provision to authorize such a (b)(3) exemption for ERDA. Mr. Moss did not comment on the specific language, but did indicate that in concept the approach of the provision was acceptable and in accordance with the preceding discussion and, further,

that he did not object to it. Subsequently, he indicated that the specific language could be improved, but again, that he had no fundamental objection to the approach represented by the draft provision. The statutory test for the class of information, consistent with basic FOIA principles, would, of course, be subject to judicial review under current FOIA procedure.

- 8. Mr. Moss emphasized that the proposed statutory language provides no authority to withhold information from Congress, or any committee or subcommittee of Congress. He also stated his belief that any Member of Congress should be able to have access to such information.
- 9. We agree that the above summary accurately reflects the substance of our meeting.

Treated **Signed,** Andre Son Son Strawned and he gible and his

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office of the attorney general washington, D.C. 20530

LETTER TO HEADS OF ALL FEDERAL DEPARTMENTS

Re: Freedom of Information Act

I am writing in a matter of great mutual concern to seek your cooperation.

Freedom of Information Act litigation has increased in recent years to the point where there are over 600 cases now pending in federal courts. The actual cases represent only the "tip of the iceberg" and reflect a much larger volume of administrative disputes over access to documents. I am convinced that we should jointly seek to reduce these disputes through concerted action to impress upon all levels of government the requirements, and the spirit, of the Freedom of Information Act. The government should not withhold documents unless it is important to the public interest to do so, even if there is some arguable legal basis for the withholding. In order to implement this view, the Justice Department will defend Freedom of Information Act suits only when disclosure is demonstrably harmful, even if the documents technically fall within the exemptions in the Act. Let me assure you that we will certainly counsel and consult with your personnel in making the decision whether to defend. To perform our job adequately, however, we need full access to documents that you desire to withhold, as well as the earliest possible response to our information requests. In the past, we have often filed answers in court without having an adequate exchange with the agencies over the reasons and necessity for the withholding. I hope that this will not occur in the future.

In addition to setting these guidelines, I have requested Barbara Allen Babcock, Assistant Attorney General for the Civil Division, to conduct a review of all pending Freedom of Information Act litigation being handled by the Division. One result of that review may be to determine that litigation against your agency should no longer be continued and that information previously withheld should be released. In that event, I request that you ensure that your personnel work cooperatively with the Civil Division to bring the litigation to an end.

Please refer to 28 CFR 50.9 and accompanying March 9, 1976 memorandum from the Deputy Attorney General. These documents remain in effect, but the following new and additional elements are hereby prescribed:

In determining whether a suit against an agency under the Act challenging its deniel of access to requested records merits defense, consideration shall be given to four criteria:

- (a) Whether the agency's denial seems to have a substantial legal basis,
- (b) Whether defense of the agency's denial involves an acceptable risk of adverse impact on other agencies,
- (c) Whether there is a sufficient prospect of actual harm to legitimate public or private interests if access to the requested records were to be granted to justify the defense of the suit, and
- (d) Whether there is sufficient information about the controversy to support a reasonable judgment that the agency's denial merits defense under the three preceding criteria.

The criteria set forth above shall be considered both by the Freedom of Information Committee and by the litigating divisions. The Committee shall, so far as practical, employ such criteria in its consultations with agencies prior to litigation and in its review of complaints thereafter. The litigating divisions shall promptly and independently consider these factors as to each suit filed.

Together I hope that we can enhance the spirit, appearance and reality of open government.

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/s/ Griffin B. Bell
Griffin B. General

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The Honorable Gaylord Nelson
Chairman, Subcommittee on Monopoly
and Anticommetitive Activities and Anticompetitive Activities Select Committee on Small Business United States Senate Washington, D.C. 20510

Dear Mr. Chairman:

On behalf of the American Council on Education, an association representing 1,490 colleges, universities, and education organizations, I would like to reaffirm our endorsement of testimony delivered by Vice President Jones of MIT before your subcommittee on May 23 and to convey our views concerning the awarding of patent rights developed by colleges and universities in the performance of federally funded research.

Colleges and universities unanimously support legislation that would permit contractors to retain exclusive rights to inventions subject to a nonexclusive, nontransferable, irrevocable paid up license in the government. We firmly believe that such uniform regulations will best achieve a policy of making inventions available to the public. We urge your support of such legislation. In the absence of support for this proposal the higher education community strongly favors the maintenance of the existing federal policy permitting diverse policies within the various federal agencies rather than vesting patent rights in the government or establishing a policy of deferred determinations.

The process of education at most colleges and universities embraces the conduct of basic research which may or may not develop a patentable item. The occurrence of an invention during the course of the research is virtually always incidental to the main objectives of the research agreement and only in rare instances provides financial benefits. An invention, when it occurs, is largely attributable to the personal creativity of the investigator buttressed by his years of professional training and experience, and to the scholarly environment and research resources provided by the university.

Since such inventions are generally developed in performance of basic research, they tend to be embryonic in nature and, therefore, usually require substantial investment of private risk capital for the further development necessary to introduction into the market. Accordingly, if university inventions are to be used, institutions must seek to interest industrial concerns who have the commercial capability the university lacks. Therefore, unless the university has the ability to grant exclusive licenses, such as those permitted under Institutional Patent Agreements, it may be unable to attract the necessary risk capital. When the government retains title, the patents are made available to all comers on a nonexclusive or even royalty free basis. This is tantamount to "dedication" of the invention to the public. In such cases, a commercial concern may often be dissuaded from investing the necessary development effort to make the product or process useful to the public.

The Honorable Gaylord Nelson

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Inventions resulting from research sponsored by Federal agencies involve equities of the government, the contractor, and the inventor. When a patentable invention is made by an investigator in an academic institution with the help of Federal funds, rarely, if ever are the Federal funds the sole or even the major factor contributing to the invention. The insight of the investigator, derived from his career working in a given field, is generally paramount. The university itself virtually always helps to finance the laboratories, equipment, and personnel contributing to the invention. an interest was an entry

If you have any questions about our position, we would be pleased to discuss it with you or your staff at your convenience.

Sheldon Elliot Steinbach Staff Counsel

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Washington, D.C. 20510

Dear Mr. Chairman: Alverse of this post lacto will processe we work of the common ways of the distance to the common ways the control of the

On behalf of the American Council on Education, an association of over 1.400 colleges, universities, and organizations in higher education, and the associations listed hereunder; I am forwarding herewith our statement for inclusion in the record of the hearings held on December 19-21, 1977, by the Senate Subcommittee on Monopoly and Anticompetitive Activities concerning rights to inventions developed under government-financed research.

Our associations endorse a government policy which permits the contractor to retain exclusive rights to inventions subject to a nonexclusive, nontransferable, irrevocable, paid-up license in the government.

The process of education at most colleges and universities embraces the conduct of basic research which may or may not develop a patentable item. The occurrence of an invention during the course of the research is virtually always incidental to the main objectives of the research agreement. An invention, when it occurs, is largely attributable to the personal creativity of the investigator backed up by his years of professional training and experience, and to the scholarly environment and research resources provided by the university.

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The Honorable Gaylord Nelson Company 13, 1978 Page Two

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We strongly support H.R. 8596, the Uniform Federal Research and Development Utilization Act of 1977, as an enlightened government policy. We firmly believe that the uniform regulations provided for in the bill will achieve the government goal of making inventions available to the public. We urge your support of this bill as a famous of the public of the description of the famous of the

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Very truly yours,

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Sheldon Elliot Steinbach
Staff Counsel

The following associations join in this statement:

American Association of Community and Junior Colleges

American Association of State Colleges and Universities

American Council on Education
Association of American Universities
Association of Jesuit Colleges and Universities

National Association of College and University Business Officers

National Association of Independent Colleges and Universities National Association of State Universities and Land-Grant Colleges

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National Catholic Educational Association, College and University Department

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Inventions resulting from federally funded research constitute a valuable national resource. The large amount of federal funds supporting research dictates the necessity of examining the government's patent policy in order to ensure that inventive results are being delivered to the public and that the equities of all parties involved are being protected. Because of their special mission, colleges and universities have unique patent concerns which warrant a detailed exploration, particularly with regard to ownership of patent rights developed on campus under federal contracts and grants.

The federal government sponsors research in universities to expand the boundaries of existing knowledge in areas or on problems deemed to be in the public interest or to be related to national goals. Universities are free to publish research results which are generally made available to all. The right to publish is normally preserved in the negotiation of grants and contracts, as is the sponsoring agency's right to receive agreedupon reports.

The generation of inventions is almost never the main objective of the research conducted with federal agency funds; rather, an invention generally is an incidental "byproduct" of the research activity, largely attributable to serendipity and/or the personal creativity of the investigator backed by his years of professional training and experience, and to the scholarly environment and research resources provided by the university. When patentable discoveries occur, the equities to be considered include those of the inventor, the university, and, very properly, the sponsors providing financial support for the particular research project most closely related to the discovery.

When a patentable invention is made by an investigator in an academic institution with the help of federal funds, rarely, if ever, are the federal funds the sole or even the major factor contributing to the invention. Beyond the critical

contribution of the investigator, the university itself virtually always helps to finance the laboratories, equipment and personnel contributing to an invention.

It also provides a scholarly atmosphere, and often the infusion of funds obtained from nongovernment sources. Accordingly, each of the parties has a claim in equity.

A policy which assigns patent rights to the government for all federally supported research, however large or small the federal contribution, eliminates the universities' ability to recognize the equities of other sponsors who contributed to the discovery of the invention as well as the contributions of the institutions themselves.

Since inventions resulting from research sponsored by federal agencies involve equities of the government, the contractor (on his own behalf or as the result of intermingled funds derived from other than federal agency sources), and the inventor, many factors must be considered in making a decision as to where the primary right in such inventions should be vested. In making that decision only one consideration should be paramount, and that is in whose hands will the vestiture of primary rights serve to most quickly and economically transfer the invention technology to the public for its use and benefit.

Educational institutions are, of course, not organized either to manufacture aliados, roberso i abrovido pas fijingili sali. or produce and market a patentable invention. Accordingly, if university-generated วารประสบให้เราสาสติดเลย arkusti esti metreem di esti (k.e.), resi inventions are to be used, such institutions must seek to interest those in the industrial grika i vodav žasta žesta bieti metalika er a u mia restilatiek — i riti, ili galerit tis etji por i mid world who have the commercial capability for invention development and also, าวเลขายาการเป็นสายเวลาเกิดได้สายเกิดให้เดือนสายเป็นสายเสียง เลยไม่สายเล้าสายเลือนได้สายเลือนเป็นเป็น very importantly, market development, which the university lacks. This is often ritualita aus confrantingo nuun quaglavel usa anasmust uli un bibullu gu sé a difficult task, since few inventions coming out of university research offer readily รูง จังคำรายการประการสูงบรรม ผู้สำหาร ก็วิจจังวิทยุพันธาสุที่ กระวันไป ก็การต่องบราก ซึ่ง สุดพัพ ที่มีรับรสุ พร recognizable prospects of a large market or a high return on investment. University-ทั้งเกาได้สอง โดการ เพิ่มเกราะหรือมาที่เลาที่เลา เรื่อง และโดยพละ คลายท่ายที่สู้ทำใหม่ คลให้เยยเลยได้ ยุลมา based inventions, since they most often correlate with the results of fundamental a alla and ligge amot me dichi mona sicali a mismora ka maktersi yate ke misia na caliscen da maga e ka

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research, tend to be, at best, in the early stages of development, and therefore require the investment of substantial private risk capital to develop the invention to the appropriate state for introduction into the market.

At the same time, universities are in a unique position to objectively seek the best qualified industrial developer and under appropriate licensing arrangements monitor the diligence of developmental efforts by such a developer. If universities cannot furnish, if appropriate, an exclusive license to developers for a limited period and thereby secure the investment of necessary capital, inventions resulting from government contracts are less likely to be developed to the point of marketability, and thus the public is less likely to receive the benefits from such inventions, or at least may not receive them as quickly as otherwise would be the case.

When the right to seek patents resides in universities, appropriate patent applications can be filed promptly and negotiations immediately commenced with prospective developerlicensees, with the active assistance of the inventor. When this right does not exist at the time of contracting, but must await a determination after the invention has been identified, substantial time is usually required to prepare the necessary documentation for the sponsoring agency and for the agency to make a determination. While awaiting the outcome of such administrative process, the invention lies dormant, with the attendant risks that the inventor's interest in assisting in the development becomes attenuated and that intervening rights of others may foreclose successful transfer of the invention to the public.

Since deadlines for domestic and foreign patent applications are affected by publication of patentable ideas in scientific journals, delays in determining the disposition of rights to an invention can result either in delay of publication of research results or risk of expiration of the time limit in which patent applications can be filed. Neither choice is beneficial to the public interest.

Although the university's primary motivation in filing and prosecuting applications for patents is the timely promotion of actual availability of new products or processes to the general public, if, in the course of such transfer, income to support further research at the institution can be generated, the public benefits a second time.

The public obtains the benefit of universitygenerated patents through
the efforts of those sponsoring agencies which offer adequate inducement to
those who can bring the fruits of basic research into a form useful to the consuming
public. Mere exclusivity in patent rights does not ipso facto create artificially
high prices for related products and royalties generally represent only a very
small fraction of the retail price of marketed goods. Moreover, one must face
the inescapable conclusion that the development of inventions under a reasonable
government patent policy will benefit the public by making available products
that would otherwise not have been available at any price.

Without exclusivity to some degree, private sources are unlikely to have sufficient incentive to invest in the effort necessary to develop an invention available to all into a product or process actually available to the public. Indeed, the investment required to bring a product or process to a marketable condition and to introduce it into the market is almost always far greater than the investment in original research from which the invention results.

To bring an invention to public use, further development or engineering usually is required, such as testing or "screening" a prototype of the new product or process. Before the efforts and expenses incident to testing or screening are undertaken, investors need to know who has the title to or ownership of the invention (i.e., the right secured to inventors and their assignees or licensees, for limited times, as provided in the Constitution).

ed i Trigonomi, di ser in me in dogi e una si, i e si escretario di ser trocci a vici de comen i nempoligia sugri e in gli debreniami sologi e dibblici i ginera cologia e la cologia di ginera de particologi di in monomi, e sulla seria descriptione colo e sologia e il tribito di comen cologia e seria de particologia di Cologia et en 31 ten contribità que a ratio escretario del particologia en di secretario de particologia e contribucione de particologia en di colori del particologia e contributa e contributa de con Sometimes prospective licensees have refused to undertake the testing, screening or development of inventions unless the licensor would grant an exclusive license for commercial sale or use. In some cases, no viable alternative has been available and, in the absence of an exclusive license, the use of the product, process or machine has been denied to the public.

Universities usually do not possess the resources, critical facilities, or controls necessary to bring drug products, for example, through the clinical states to marketability. Thus, it is imperative that they be in a position to supply an incentive under appropriate licensing arrangements to those organizations which have those facilities and control capabilities.

Since government personnel would not be as intimately familiar with the flash an invention as those that have developed it in a university, they would be in a second an much less favorable position to ascertain or pursue the commercial marketability of such an invention and it is feared that the time that would have to be invested in such activity could well cause a significant reduction in invention disclosures from university researchers, with a consequent reduction in public access to potential of fruits of research.

Thus, the primary result of the economic stimuli afforded by a realistic volume licensing policy is a public benefit, the production and introduction of a good or realistic volume service, that otherwise might not become available in the context of our free. The light of enterprise system.

behalf of the government, normally asserts its rights to ownership of any inventions and patents generated in the course of research sponsored and funded by the agency but does have regulations under which such right can be waived to the contractor or grantee. If an institution desires to acquire title to a particular invention, it must request a waiver in accordance with the regulations of such agency. The granting of a waiver generally depends on a determination by the agency, based upon evidence submitted by the contractor or grantee, that the invention will be more adequately and quickly developed in the public interest if title to the

invention is waived to the contractor of grantee. Such waivers are given with a reservation of a license to the government to practice the invention for governmental purposes and with other provisions which adequately protect the public interest.

An alternative to the "waiver" approach is the "Institution Patent Agreement" approach, available since 1978.

This approach, endorsed by a 1968 GAO Report, permits the grantee institution to retain title and to administer the principal ownership rights in inventions made under department grants and awards, clearly defines the rights of the parties with respect to such inventions, and sets forth general guidelines governing the licensing of inventions. It includes limitations on the duration of exclusive licenses to be granted, it reserves a royalty-free license to the government for governmental use, and it provides other appropriate safeguards to protect the public interest. These latter safeguards include a reservation to the government of the right to require the granting of additional licenses on royaltyfree basis or on other terms that are reasonable under the dircumstances, where such licenses are necessary to fulfill public health, welfare or safety requirements.

With the active assistance of inventors, the universities are in a better position than the federal government to transfer technology to the public through the economy. A government "title" policy, however, would preclude the university from recognizing the equities of others, including inventors and nongovernmental sponsors, and would fail to acknowledge the benefits that now accrue to the taxpaying public for its contribution to the institutions research efforts.

Consequently, qualified universities that have developed a technology transfer capability should be granted, with the award of a contract or grant, a first option to title in inventions generated on their respective campuses with federal funds with appropriate safeguards to prevent abuse of patent rights retained by any such institution and to minimize any anticompetitive effects.

^{1. &}quot;Institutions Patent Agreement Governing Grants and Awards from the Department of Health, Education and Welfare" HEW Standard Form Rev. 8/26/68.

^{2.} Report to the CongressProblem Areas Affecting Usefulness of Results of GovernmentSponsored Research in Medicinal Chemistry-Comptroller General of the United States -B 1640 31(2), 1968

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HOWARD L. ROSE

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The Honorable Caylord (Nelson size of the best of the best as a both of the best of the be United States Senate Washington, D., C. 20510 sign makes a large engine on a rejection of the commence of a proposition was

Dear Senator Nelson: 33 popularies como emisente da vida exemple establishe de a copenial de a

Reference is made to a recent conversation between Mr. Gerald Sturgess of your staff and Ms. Dorothy Bomberger, Program Manager, United States Activity Board, of the Institute of Electrical and Electronic Engineers (IEEE) concerning hearings to be held by your Monopoly and Anticompetitive Activities Subcommittee on Amendment No. 187 to the GSA Federal **Procurement Regulations : This letter is written in response to Mr. Sturgess 10 0200 suggestion that the Institute submit its views on the rights of Universities secting inventions made pursuant to research funded by the Federal Government.

The IEEE has become increasingly concerned in recent years with the decline in the technological growth of this country and its loss of preeminence in the field of science. The Institute has thus taken an increasingly active roll in supporting programs and policies which are calculated to restore a fertile climate for innovation in this country and which in fact will accelerate the pace at which technology is developed.

In support of this effort the Institute has supported programs that it believes will promote such goals as well as opposing programs believed to hamper them. The Institute believes that the source of all creativity is individuals, and that the individual will disclose and develope his or her inventions if he or she can benefit from such. Thus, the Institute supports programs that reward inventors for their inventions and which leave all avenues of financing open for development of their ideas. In this latter context, it is essential to destroy the myth that important inventions result substantially only from the efforts of big business and that the retention of rights by Government contractors in inventions made under Government contracts will only cold benefit such companies usually at the expense of the public. Such a philosophy in effect denies federal funding of inventions of individuals, universities and small business.

RIGHTS FOR INVENTIONS PROPERTY OF THE PROPERTY

As indicated above the Institute is concerned with increasing the rewards received by individual inventors as a result of their creativity. This concern is shared by many highly placed individuals both in and out of Government. Reference is made to testimony by Admiral Rickover before the 87th Congress, wherein he stated: 250 per or area per car at think you also be the conditional

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". . . one of the two major problems facing the patent system is how to increase incentives for employed inventors who get no benefit whatever out of the patent system as it has evolved. We might well consider whether we ought not to go back to the original intent of the Constitution and devise some reward for inventors whether they are government or industry employees."

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If the Government acquires title to all inventions stemming from federally funded R & D, about \$26 billion in 1978, a large segment of the Institute's members are henceforth denied any opportunity to "participate in the rewards of their inventiveness." The contractor receives no award for inventions so that nothing is available to pass on to the inventor. Both the inventor and the contractor lose interest in disclosing inventions. In this context it should be noted that over the period 1970 through 1976, total invention disclosures to Government agencies from Government contractors fell 30% from a high of 7,896 in 1970 to 5,537 in 1976. However, the invention disclosures in which the Government acquired only a license fell from 1279 in 1970 to 1115 in 1976, a decrease of only 15%.

It is a well known fact that the U. S. has fallen to sixth in the number of patent applications filed by its nationals on a per capita basis. The reasons for this phenomena are not fully understood but the decline in U.S. pre-eminence in technology is quite apparent. It is believed that closing the door on the hopes of the engineering and scientific community to acquire greater benefits from its labors will only further exacerbate an already potentially dangerous situation. Men have not, so far as this writer is concerned, changed their views concerning their rights in property since 1795 when Mr. Justice Patterson of the United States Supreme Court stated "Men have a sense of property... The preservation of property... is a primary object of the social compact."

THE PRIVATE INVENTOR - TECHNOLOGICAL BREAK THROUGHS

Much of the opposition to the Regulations results from the assumption that the policy inherent therein is good for big business and is detrimental to small business. The essence of this thesis is that (1) most important inventions are derived from big business and (2) small businesses do not contract with the Government. As to the first point, such recent major developments as xerography, instant pictures, optical character recognition, magnetic core memories, vacuum tubes, F.M. radio, lasers, penecillin, jet engines, pregshrunk fabrics, zippers, color photography, bakelite, cellophane, foam rubber, cross-sectional X-ray imaging apparatus (CAT), mercury dry cells (later perfected under Government funds) to name a few, were the inventions of private individuals or universities. Many of the individuals founded small companies to develop their inventions. A large number of the above listed inventions were developed to some extent or another with the use of Government funds with the patents remaining with the contractors. Would these individuals have sought Government money if all of the resulting patents had been assigned to the Government? And if not, how many years would the public's benefit from the inventions been delayed? The way of sweet the colors of the state of the sales of the trati Andrea (1. berne 2011) de de la compositorio de la compositorio de la compositorio de la compositorio de O Caligna (1. compositorio) de la California de la California de la California de la California de la Californi

The Honorable Gaylord Nelson May 15, 1978

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To deny any institution, company, group or individual, regardless of circumstances, the rights to their Government funded inventions is a drastic measure which will stultify the development of inventions. Regardless of statements to the contrary, the significant inventions are the work of small companies and individuals. The large corporations have abdicated this role to a great extent; they have publically stated that they no longer do research and only step in when a product has shown promise.

True, each of the aforementioned products has produced or ended up in a large corporation, but one must wonder what would have happened to those inventions if patent protection were not available. Would an individual dedicate five, ten or more years to a product if others could reap the benefits of his efforts and sacrifices. As a very recent example, the presently most effective oil slick pick-up apparatus is the work of one man who dedicated seven years of his life before he realized a profit.

As to other products actually developed and introduced by small companies, massaging showers were introduced to the market place by a very small company that developed considerable know-how in the field of fluid technology under government contracts. High powered machines for commercial irradiation of plastics and for sterilization of medical supplies were developed by a small company partly with government contract funds. namen a vigili i na nastavina maš

It is believed that the above facts go a long way to refute Admiral Rickover's statement to this subcommittee that "most of the major advances in technology in the past 20 years have come in areas where Government invested heavily, such as space, defense, and nuclear energy". It would appear more appropriate to say that most of the advances in hardware, of the type in which essentially only the Government has any interest, has been funded by the Government. This is as it should be, but even then the Government usually buys its hardware from the contractor who did the R & D. Yet, much of the opposition to the Regulations on Capital Hill and elsewhere appears to stem from the belief that the Regulations go too far in the direction of allowing profit-making firms to benefit from federally funded research. However, only profit motivated companies will bring the results of such research to the general public. Well known instances of federally funded R & D benefiting the public through the auspices of the Government contractor are: Corning ware through Corning Glass, massaging showers, aircraft in general, airport ground control, computer industry through UNIVAC, atomic energy through Westinghouse, radio through RCA which started as a Government laboratory in World War I, magnetic seals on refrigerators and many, many more. The second of the s

Numerous representations have been made for and against the necessity to grant exclusive licenses to insure the development of a product in this country. In the twenty-four years that this writer has been actively engaged in licensing inventions, he has encountered many instances where non-exclusive licenses were quite saleable and many others where only exclusive licenses could be sold. The type of license that can be sold in any given situation is determined by many factors, including the funds required to be invested in developing or marketing the product and the ease with which the product can be copied. The

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larger the monetary requirements and the more readily the product can be copied, the greater the pressure for exclusivity. Further, in such cases the cost of bringing the produce to the market place to the Company that did the ground work in the particular area involved may well be less than to others in the field. It would appear that the prime concern to the Government should be to have the invention reach the market place at the least possible cost to the public which, afterall, pays all the bills in the long run.

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BALANCE OF PAYMENTS

The above statements, as indicated, apply to the U.S. They do not apply, however, to foreign countries. Companies in Western Europe, in particular, require exclusivity. They want exclusive use of know-how and exclusive rights under patents. Without these they will for the most part go their own way which often includes using U.S. inventions not covered by foreign patents. With the balance of payments of the U.S. constantly running in the red, large losses of foreign source income resulting from reduced sale of technology abroad only adds to the problem. Foreign companies are willing to pay large sums for U.S. know-how and inventions. A very small company of which the writer is aware is presently engaged in preliminary discussions with a European company concerning transfer of exclusive rights to know-how and European patent rights for a single product having a sale price to the user of about \$3,500. The payment for such rights will include an initial payment in the neighborhood of \$2 million, plus a royalty on sales. Without the foreign patent rights this sale could not be consumated.

It is believed that by forever denying inventors, institutions and companies any opportunity to benefit from inventions made under Government contracts the U. S. decline in technology will be accelerated and one of this countries major exports will be seriously impaired. It must be remembered that if the U. S. is not exporting technology, it is importing it.

It is requested that this letter be spread on the record of the aforesaid hearings.

Howard L. Rose

Task Force Leader - Patents United States Activity Board

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Mr. Gerald Sturgess Room 424 Russel Senate Office Building Washington, D. C. 20510

Dear Mr. Sturgess:

Sugeral County Exchange in Ingy we know that in the prestation As promised, enclosed is material from the Department of Commerce on Agency Statistics on Patent Practices - Fiscal Years 1970 through 1976.

If I can be of any further assistance, please do not hesitate to contact me. The control of the contr Sincerely yours,

Howard L. Rose

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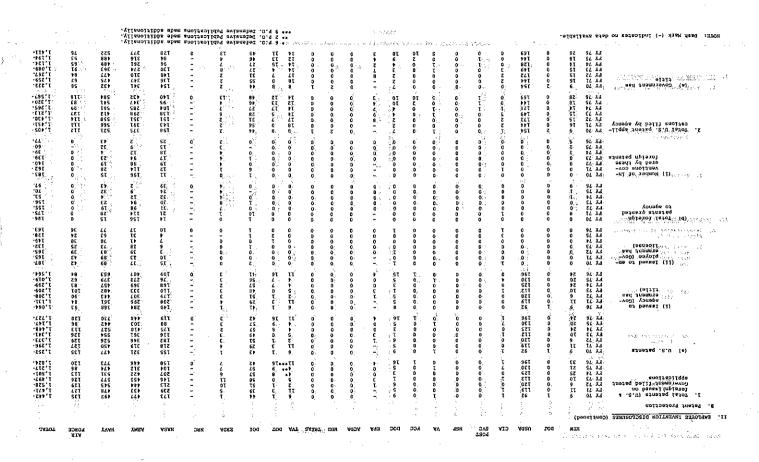
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Enclosure

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TABLE I
AGENCY STATISTICS ON PATENT PRACTICES - FISCAL YEARS 1970 THROUGH 1975

	REW	DOJ	USDA	CIA	POST	NSF	VA	PCC	DOC.	EPA	ACDA	WID	TREAS	TVA	hov.	DOI	ERDA	NRC	NASA	ARNY	NAVY	AIR FORCE	TOTAL
I. INVENTION DISCLOSURES REPORTED		-	ODDA	CIA			*24			LIA	ALUA		Incha			201	LADA	NA.	Auga	ANNE	MAVI	PORLE	IOIAL
A. Total invention disclosures	PY 70 286 FY 71 275 FY 72 216 FY 73 230 FY 74 284 FY 75 260 FY 76 340	0 1 2 1 3	184 162 386 143 123 131 194	27 23 21 15 12 8 8	70 66 22 87 28 18	53 56 59 84 89 157 186	10 18 19 23 13 16 28	0 0 0 0 0 11 10	42 87 75 117 90 63 86	30 62 32 23 58	0 0 2 2 0 0	2 0 0 0 1	0 0 0	53 52 51 43	111 162 38 47 44 104	182 154 166 146 135 134 162	1420 1502 1129 1228 1170 1125 1530	-	3042 2475 2455 2147 1676 1130 1676	1708 1675 1444 1095 1061 998 1161	2045 1954 1789 1577 1599 1585 1908	1591 1475 1383 1181 1259 1033 950	10,829 10,141 9,789 8,237 7,661 6,839 8,426
1. Gövernment employee disclosures	PY 70 24 PY 71 60 PY 72 35 PY 73 27 PY 74 24 PY 75 39 PY 76 50	0 0 1 1 1 0	151 152 139 141 119 127 191	11 15 14 7 4 2 5	31 31 17 28 16 6 21	0 0 0 0	10 18 15 19 8 14 25	0 0 0 0 11 10	36 75 62 57 69 38 69	9 5 4 3	0 0 0	2 0 0 0 0	0 0 0 0 0	49° 53 52 51 43 32 58	12 32 28 16 22 17 26	87 76 85 70 71 72 100	12 19 20 6 8 35	-	410 350 256 283 261 259 333	850 843 842 584 572 619 771	994 960 976 898 896 898	247 204 216 143 126 146 188	2,933- 2,888- 2,764- 2,336- 2,244- 2,318- 2,889-
2. Contractor-disclosures	FY 70 262 FY 71 215 FY 72 183 FY 73 203 FY 74 260 FY 75 223 FY 76 290	D 1 1 1 2 2 2 2	33 10 247 2 4 4 3	16 8 7 8 6 0	39 35 5 59 12 12	53 56 59 84 89 157 186	0 4 4 5 2	0	12 13 60 21 25 17	21 57 28 20 46	0 2 2 0 0	0 0 0 0	0	0 0 0 0	99 130 10 31 22 87 17	95 78 81 76 64 62 62	1408 1483 1109 1222 1162 1090 1501	01,11,1	2632 2125 2199 1864 1415 879 1343	858 832 602 511 489 379 390	1051 994 813 679 703 687 910	1344 1271 1169 1038 1133 887 762	7,896 7,253 6,525 5,901 5,417 4,521 5,537
II. EMPLOYEE INVENTION DISCLOSURES						:																	•
 A. Determination of Government Rights in U.S. 	1. 1.			;			Ä	:	1			ż	- 1	·							í	•	
 Total invention disclo- sures for which Govern- ment rights in U.S. have been determined 	FY 70 37	0 0 1 1 1 3	146 143 131 136 131 138 195	11 15 14 7 4 2 5	19 24 11 25 16 6	0	4 5 10 8 8 6 13	0 0 0 0 11 10	23 42 26 27 37 19 31	7 4 3 4 3	0	2 0 0 0 0	0 0 0	49 53 52 51 43 32 58	7 27 19 10 14 21	97 76 95 70 71 72 100	8 19 9 29 10 4 18	-	181 159 167 144 108 99	431 439 442 399 324 402 351	525 575 565 417 569 541 656	137 134 126 155 102 100 108	1,671 1,736 1,697- 1,517- 1,467- 1,494- 1,778-
(a) Government has title	PY 70 35 FY 71 22 FY 72 31 FY 73 30 FY 74 24 PY 75 33 FY 76 43	0 0 1 1 3 1 1 1	146 142 131 135 124 129	6 3 1 1	1 0 3 2 12 6 4	0 0	0 1 4 3 1	0 0 0 0 0 11	13 22 17 17 16 13	7 0 1 4 3	0	2 0 0 0 0 0	0 0 0	53 52 51 43 32 58	3 25 14 10 12 21 15	77 69 73 62 63 66 92	19 9 29 10 4 18	- - - - 0	154 136 140 130 96 84	382 363 401 345 302 343 291	432 475 477 363 489 488 584	86 70 70 106 65 53 76	1,397. 1,401- 1,432- 1,287. 1,262- 1,289. 1,531-
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tt.	EMPLOYEE INVENTION DISCLOSURES (Continue	ed)																				7		,
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	J. Total foreign patent. FY 70 applications filad by PY 71 or on behalf of agency FY 73 FY 75 FY 75 FY 75 FY 75	0 0 9 26 3	0 0 0	0 0 0	5 0 4 0 0	0000	0	0 0 1 0 0	. 0 0 0 0	0 0 0		000000000000000000000000000000000000000	000000000000000000000000000000000000000	0 0 0	000000	0 0 0	0.00	27 0 15 0 0	- - - - - 0	43 26 57 152 62 27 49	89 39 3 7 1	22 12 39 31 7	0 0	167- 104- 103- 222- 97- 33-
	(a) Number of inventions covared by Fr 70 these overeign Fr 72 applications Fr 73 Fr 74 Fr 75 Fr 76 Fr	0 0 2 3 1	000000000000000000000000000000000000000	00000	5 0 1 0 0	0 0 0	0 0 0	000000	0 0 0 0	0000000	0 0 0	0 0 0	0 0 0 0 0	0 0 0	000000	0 0 0 0 0	0 0 1 0 -	1 5 0 2 0 0	5	.7 4 6 21 9	89 39 3 7 1 1	22 12 39 31 7	0 0 0	124- 60- 49- 64- 20- 7- 17
	4. Invention disclosures PY 70 for which a determina- YY 71 tion was made not to PY 72 file a patent appli- cation but to publish PY 73 lastead PY 75 PY 76	21 .7 .7 .9 .9 11	0 0 0 0 3 1 20	7 11 6 6 25 29 19	0	0 0 0 0	000000	0 0 0 1 0 1 0 1 0 0	0 0 0	1 15 7 9 3 7 6	0 20 0 2 4	0 0 0 0	00000	00000	14 12 20 26 25 20 47	1 0 1 0 0	0000	3 2 1 3 0 5	-	0	0 0 0 2 2 2 5	0 0 0 0 0 0 6 6 62	000000	47, 50- 41- 73- 71- 73- -158.
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g/ Substantially all of these disclosures were turned over to the Government pursuant to contract clauses which gave the contractors the option to retain title by filing a patent application and the contractors elected not to do as [III.A.] - Army, Air Force, 1970-1971.]

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NOTE: Dash Mark (-) indicates no data available.

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unless a new determination was made as to the type of patent rights clause to be used in the modification, smendmont, remewal or continuation. [19.A, Text].

Chedifications; amendments, renawals or continuations to contracts and/or grants were not counted,

* (G) (F) gue (T) (e) (J) sug I(e) (S) (S) . *Clause included in all HUD contracts - part of General Provision form. tis to control of the "(1'00'I) 10 (0) (0) (0) (0) (560T) (Z) (0 1,943. 94 X4. dential Policy) ** LZZ ##004T 1(9)(1) Of Prest. (ET9 10 (ō) to 10 to (ō to (0) 101 (0) (ŏ ιō 1975) (tor redniation (Section 17 15 ESB 'nÞ 222 120 ph doneruments; 1 10 (o) {0} lo (0 (0) to will be required for FY 74 1795 ĎST Ťτ CIVI FRE OF WITCH 1 1666 **{-**₹0 (a) (0) (0) (0) 10 (0) (SBE) (OT) (o) (ŏ (0 (0 10 TUESUAGE TOT COMMEE-1,078. 125 £6T 7/6 09 products, processes, FY 72, or methods which are 111 ŧο ١ (p) (q) (O) (0) (0) (TT) (0) (0) (0) 10 (0) (0 ((1-L D (0) to '6TZ 1.1 EST Zτ ·(ET) (ö) (0) (0) develop, or improve ٧ň 3 ton (0) fn **{**→} €0 fa ſΩ 1-1 10 (0 (0,) (0) fa 1 (-) (61) (0 CYACE WAS SO CERTER, 109 T/ 12 33 Decause a principal (0.) (0 (ŏ (0 (-1 (0) {0 (0, 1) 210 357 622 Ö ā nr 'xa (Te*051) (-33) (T082) (01 (a) [19] (a) (RYE'TT) 15 ſſ (485 [0 3 ŧσ (-) (o) (o) (0) (0.3 60 - 86/ 'FT źττ £54 615"1 721 ĭ toz 791 -592 GOLT 6T · 5 τ OZI 692'9 94 34 (15'828): (0 (0 {27b } 1-) (0 (057) (6) (6) (0) (8) (ē) (ZT9) (õ) (n) ſō ILS 1 (ó (409'TT) -851.8 1,426 96 PK 75 4,226 886 **461** 69E 232 129916) 1 (0 {29} } (-(£0Z) (0) (0) (0) (273) (0) (21) (0) (o (-) 105) (0) (E8E'8) (E 3) 522'1 60E 77 99 428'T 7/ Ad EE9 BCT 213 450 (6 (518) (-EQ. (58) (o) (o) (0) (ZT) (0) (58E) (TE) (6) (0 (-) (60) (05) (445'5) 10 co Tuneurrous 'S6C'S ιzτ TRB 159 SZE īΒ LET E94'T E4 34 565 Ţς 24. OF EXCLUSIVE FLORES (178'ET) (552) (0) (ZSL) (PP) 10 (857'TT) (0 } t n 1567 (-(0 (0) (0) (0) 4E 1 (0) (0)) (0 ž, 346 EK 15 3'406 acquire principal -cne's FET 202 f 87 'T 16T 69Z Z6E • • ELE ment acquires or may (-(0) (-) (12) (-) (0) (õ ([18'8] {251'6 } 10 3) J). 10 > (9EE) to ٠, (102) (6) (6) (0) (0) (0) (0)) (0 EA 11 1'863 DUDGE WITCH FUE CONCEU-· car'b 611 159 59Z'T 207 738GV P91 29 PT . זכז SCETOUS PRATUG CTWOSES (10'569) (a) (0 'n (555) (--(0 (E67) (6) (6) (0) (0) (-) (0) (0 Œ (0 Mumber of ReD contract 133 ZII 092 233 278 īπ 02 135 ٥ £4.30 T'993 (JSE) (JOSS) [(a) (nez'at) (a) (0) (19) {o `) (590'41) (55'178) (0) (98) to. (0) (0) 115'1 99 zτ OZT 91 012'9 9L X4 51'502-161 2 3,168 149.2 154 742C 161 592 T 105 £8. (e', aa-1) (o) (-) (LS) (£9.) (4£9'\$T) 16921 10 . (23,577). (£21 (112 (22) ţ0 (0) (0) (0) 10 (213) 1. 5 344 TY 75 4,230 99 T4'853: 695'2 851 2 304 198 5.9 Łξ (e) (TZS'9) (05E'0T) (LSS'8T) (277) 11.02 (291) (fo. (EOZ) (0) (0) (a) (£ 1 (213) (0) (98) to (-) (05) (0-) 12,372-08617 2111 52E Z 1,244 TPT 550 BIE ВB 628'T \$4 A.E. 85.5 *(BT8'IT) (-(0) (0) (0)) (586) (68) (a) (SST'1) (-) (66.) (os) ITZT. ſū SOT) (BLZ.) ſa ISE) íò οz 121 £55'E 978 7 OCT EBE FLD -TET'ST 3,225 or R 960 TS (0) (a, 68d) (d) (T) (T98'ZT) **:**(-(o) (a) (D) 10 (ZE) (561'02) LSSZ (E6Z) (252) (0) (454) (and of 1, 2, and 3 below) 01 246 72 EK 32 3 410 .TOE. AT 149'7 £99 792'T 791 256 0 FLE ac 041 E Tree during Liscal, year ζ-(TE) (0) (0) (00) (0) (-) (0) 185 1 (102'01) (33e) I'ssi (n·) (068'ST) (BLC) 575) to (S¢T) (a) (a) (0) (0 238.1 07 YY Sonitron GA 30 Tedmin Lesor (25.01) Sonitron Solution Solution 13.0(10.325) 1300.1 17 YY -2012 made benefit 17. 13.000 Ć. ĪST 61 -616'11 T65 E 2,233 7 154 550 BSZ 385 0 49 RT 19 (0) (0) (009 C) (SZE'OT) t-(0) (0) (0) (0) {~} 11 (Z6) 100 (n teet (EEE) (0 (E6F) (9 (0 11,269. TSE'E ZET'Z 75E T Z/Z'T 315 EES DIE ō ttt 84 735 51 IA. OPERATION UNDER PRESIDENTIAL PATENT POLICY

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NOTE: Dash Mark (-) indicates no date available.

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3. Requests by contractors for

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h/These statistics were not collected prior to PY 1975. [Sections VI.A.3.(a) and (b)]

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SUBCOMMITTEE

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United States Senate

COMMITTEE ON THE JUDICIARY SUBCOMMITTEE ON THE CONSTITUTION WASHINGTON, D.C. 20510

June 21, 1978

The Honorable Gaylord Nelson United States Senate Washington, D. C. 20510

Dear Gaylord:

I have shared your interest in the proposals for revising the federal government's patent policy and have been interested in the hearings that you are conducting before the Senate Select Committee on Small Business.

Of particular concern to me is the need to formulate a new approach to patent policy with respect to discoveries and inventions arising from government-financed research in our colleges and universities. In all of our patent policy we must put foremost the ultimate best interests of the American public in benefitting from new develop-ments. Our policy must both provide incentives for such developments and assure their application and availability. Both considerations must be present in our patent policy concerning government-financed university research. Dr. F. N. Andrews, the very highly respected Vice President for Research and Dean of the Graduate School at Purdue University, has compiled the enclosed materials which I believe reflect the considered thinking of many of our colleges and universities regarding government patent policy. I share much of the concern expressed in these materials, and I would greatly appreciate it if you would make them a part of the hearing record in the hearings you are continuing today.

I look forward to learning of the conclusions of your hearings and working with you to formulate a policy that will protect the legitimate needs of the government and insure that new discoveries and inventions resulting from this research are fully utilized.

Birch Bayh United States Senator Enclosure #1.

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Publicly supported academic institutions have long had an objective to encourage the development of new knowledge and new ways of putting knowledge to practical use by publication, oral presentations and patents? We finally believe that such information must accrue to public benefit. Many of these benefits can only accrue through the patent system.

Most academic institutions receiving federal funds for support of research have a well-defined patent policy which (1) stimulates creativity, (2) encourages industry to invest risk capital to bring technology to the market place for public benefit, and (3) protects the public interest.

The vast majority of inventions at academic institutions are embryonic in nature. Without risk capital to bring these inventions to the market place, said inventions will never accrue benefits to the public. Without proprietary protection, no company can justify investing millions of dollars in an embryonic invention to get the technology to the market for public benefit. Neither the academic institution nor the federal government is likely to invest the resources necessary to develop the invention to a marketable product or process. A government policy of taking title to inventions and non-exclusively licensing to one and all has not and will not attract risk capital. Consequently, not the government nor the academic institutions, but the public, whose money was invested in the research, will be the major loser.

At the end of FY 1775, the United States Government already had title to over 27,000 patents with only about 1300 (approximately 5%) livensed. Therefore, approximately ninety-five percent (95%) were not contributing to the health, technology, and general welfare of the country. It is questionable if the best interest of the country is served by vesting title to inventions in the federal government.

ME WINDLESSE BLE

A recent survey of forty-eight (48) academic institutions by the Society of University Patent Administrators showed that fifty percent (50%) of the patents titled to those institutions were licensed. This is a marked contrast to those titled to the United States Government. An invention made with public funds only benefits the public if used. No benefits accrue if the patent is only a statistic in the Government archives.

Any action or legislation affecting government patent policy should have only one group in mind - the public that has paid for the research. Any action taken should maximize the public benefit.

In my time remaining, I would like to share with you some examples of the results of a patent policy that we have here at Purdue Universit; which (1) stimulates creativity, (2) encourages industry to invest risk capital to bring technology to the market place for public benefit and (3) protects the public interest.

CASE I

In 1969 a graduate student at Purdue, working with a heat transfer problem, conceived what he thought to be a new design for a compressive that would have cooling applications in the automotive in justry. The new design was thought to be insefficient for automotive uses. Nevertheless, Purdue Research Foundation a reed to provide limited funds for further work at Purdue, and to patent this device if the inventor could prove that it worked.

To make a very long story short, the device did work, basic United States Patent Number 3,686,893 was obtained on the device by Purdue Research Foundation. We contacted over 75 companies, both large and small, and no one was interested in licensing the technology. Finally, an exclusive license was granted the inventor and he formed his own company, to see if he could attract the necessary venture capital to perfect the device and to bring it to market.

g energies (1) geeleen, nie gebeur 2005 in 1900 dat en bestellt deele ende dat bis bis bis nichterstellig der Ausball ein die 1905 in 1905 in 1905 deele ende ende ende bis bis At the present time, this company is marketing prototypes of the device and it has raised over \$10,000,000 in venture capital based on its backage of technology which is protected by the basic patent mentioned plus patented improvements.

raid and possible technology takeover by a large corporation is the company's patent position and exclusive license agreement with Purdue Research Foundation.

One of the concerns of the risk capital venturers in the company stock from the beginning has been the strength of its patent position and the licensing arrangement with Eurque Research Foundation.

and read the control of the first of CASE (II) for any other a section of the second

One of our staff members in Horticulture, Professor Philip Nelson, is a student of the tomato industry. Philogenetical that one of the problems of the small producer was that product sales predictions had to be made in the fall within two or three weeks of the harvest for the entire year shead. The reason for the decision is that no small producer could afford huge refrigerated product storage facilities for the tomato product in bulk, and hence the product was canned at harvest into catsup, paste, juice of what have you and so the entire pack was always committed for the coming season - the packer could only hope that had enough satsup and not too much juice, and the small packer was almost never right - the big producers weren't either but they could be ther afford to be wrong.

So what did Phil Nelson do? He teamed up with another staff member, Professor Clenn Sullivan, an expert in agricultural economics, and they decided after market analysis, that partially processed temato product could be stored economically in unrefrigerated tanks. This assumed that an efficient valving and sterfliration system could be created that would permit unrefrigerated storage of tomato product, which would then make the economical acceptable to the smaller packers.

with a discretificate philosophical province in control in a con-

and, againsto make asvery long story short, funding was obtained for a research grant for them from Bishopric, a medium-stred so company in Cimainnati, Onio, that had the know-how to fiberglass line tanks which was a necessary part of the system they know they would need a Such support was possible because we were able to assure Bishopric an exclusive license to practice any technology developed.

Technology was perfected, patents were obtained and assigned to Purdue Research Foundation and as part of the agreement, the technology was dicensed exclusively to Bishopric.

In 1976 the Institute of Food Technologists Mehievement of Award was made jointly to Bishopric Products Company and Purdue University by the food industry for their significant contribution. This was the first time this prestigious award had been made to a university. The food of the prestigious award had been made to a university.

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not Not aller our staff and student inventors create new cost industries of broken block response it was are a series of posts on both

But many do make some significant scientific contributions that probably would not result in any useful product if we could not patent these inventions and license them to industry.

Professor in 1973 and in the course of his work he became dissatisfied with the results he obtained from the standard gas thromatographic electrolytic detector at that time.

Randy worked on an improvement, and he approached Purdue i Research Foundation about a patent. The Foundation contacted of its and they agreed to pay for patenting costs and to give some further research support of they could have an exclusive license on the device when, and if, it was perfected — at that point there was no assurance that it would be with a count its angle of the second in t

However, I am happy to apport that the scientific community now has a new detector commercially available, it is called the

Hall Detector and it is protected by various U.S. Patents, issued in the name of Randy Hall, and assigned to further hesearch. Foundation.

CASE IV

Now we are confronted with new challenges, especially in the energy field.

One of our scientists, Dr. George Tsao has apparently come up with a highly efficient process for conversion of a wide range of plant materials into glucose, and then easily into alcohol.

One of the plant materials that can be so converted is corn, another is rugar cane, and even crop residues can be converted by this new process.

At this time I have directed the Foundation to give Dr. Tsao whatever a distance is necessary to bring this new process to commercial realization in the shortest possible time. The usual questions will be asked of the Foundation, what does the process do, will '+ work, is it economically feasible, and what's in it for us?

Gentlemen, the last question is the heart of the free enterprior system and the one to which every innovator must respond if he hopes to see his dream become reality.

I do not know at this time if the United States Government wants to fund the massive research and commercial effort that will be required to commercially utilize the Tsao process, I don't even know if it will ever prove economically feasible to do so. I don't know if it would be a good risk for the United States taxpayer to fund the entire research effort on the Tsao technology. But if they den't, and if we ever want to give this new process a chan o to succeed in the foreseeable future, we must make the hard ducisions in concert with one or more industrial sponsors who are willing to risk their funds, and perhaps even their corporate futures, on an enterprise of this magnitude. If we are successful with this process, we could have one of the many partial solutions to one energy crisis of the future. If not, then somebody is going

to lose a lot of what can only be called "venture capital". And remember, all the other inventions I have mentioned were just as speculative in the early stages of their development as the Tsao process is new.

Should the public bear all of these costs of technology implements: on, or should we continue to let these costs be borne by free enterprise as has largely been done in the past, with the assistance of a viable U.S. Patent system?

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Enclosure #2

WIE CHAIRMAN

AN J. MCINTYNE, N.H. ... LOWELL P. WEICHEN, JR., C.

HENDERT L. BPIRA, CHIEF COUNSEL

United States Benate

SELECT COMMITTEE ON SMALL BUSINESS WASHINGTON, D.C. 20510

> Colored a water burnett TO A SHOPER OF . a D. R. we say A op. 11

F. N. Andrews F. N. Andrews
Vice President for Research &
Dea of the Graduate School Graduate House East, Ste 160 West Lafayette, Indiana 47907 | Strand Later Managary Laboration in the Talke and profit is an only being recording the recording

Dear Mr. Andrews:

Thank you for expressing your interest in the study of Government patent policy undertaken by the Monopoly Subcommittee of the Senate Committee on Small Business. on Small Business. I police in the second field the second second

To indicate the progress of the study, I am enclosing a recent press release announcing that the Office of Management and Budget has granted my request for a stay in the effective date of a procurement regulation which would permit wide use of an Institutional Patent Agreement giving universities and nonprofit organizations first option to own the rights to inventions resulting from Government-sponsored research.

The stay of 120 days will allow the subcommittee to hold hearings on the history, legal basis and implications of the Institutional Patent Agreement as an implement of Government patent policy. Hardand a 4 2 1

Hearing dates have not yet been set. If you wish to be kept informed of the progress of the hearings, please let me know.

Also, I am interested in your mention on two new small businesses having been formed within the last two years from patents licensed by Purdue University. If you could supply information on your licensing process and the formation of these businesses, it would be most helpful. makes administration of electric Washington (Contract)

Chairman

GN/gsy Encl.

PURDUE UNIVERSITY OFFICE OF THE VICE PRESIDENT FOR RESEARCH AND DEAN OF THE GRADUATE SCHOOL

April 20, 1978

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Senator Gaylord Nelson
Chairman
Select Committee on Small Business
United States Senate
Washington, D. C. 20510

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Dear Senator Nelson:

Thank you for the opportunity to present case histories of some small businesses that have been fostered by a transfer of Purdue technology.

First, it seems appropriate to state the general overview of Purdue 2018 University as it relates to technology in general.

Our institution, as well as many other publicly supported academic institutions, has long had the dual purpose of development of new knowledge and implementation of such knowledge in a practical way, which implementation may be accomplished by publications, seminars, extension services, and all of the many other ways in which the University disseminates knowledge, including the use of the patent system.

The mission of our University, as it pertains to research, is directed more to the acquisition of basic knowledge than it is to the developmental side of research.

However, sometimes in the discovery of basic knowledge and application of it to practical problems, embryonic patentable inventions appear. It is not the University mission to invest venture capital to bring these inventions to the marketplace, which in reality is the only form where such inventions will ever benefit the public. According to the Society of University Patent Administrators, at the end of fiscal year 1975, the United States government had title to over 27,000 patents, of which only about 1,300 were licensed.

On the other hand, a survey of 48 academic institutions by the same

Graduate House Fast Suite 160 West Lafayette, Indiana 47907 Security Metabolic Filipa B Aleman 2001 1978

Senator Nelson Page 2 April 20, 1978

Society showed that 50% of the patents titled to those institutions were licensed. The difference in licensing practice between the U. S. government and the typical academic institution may provide part of the explanation for the large difference.

The government typically offers licenses to all comers on a royalty free, non-exclusive basis. Universities such as Purdue, through its agent Purdue Research Foundation, typically offer exclusive licenses to those companies or individuals who are willing to invest sufficient venture capital to bring the patented idea into the marketplace for the benefit of the consumer.

Underiably Purdue University has licensed much technology to some of the largest corporations in America, but, on the other hand, many small companies have also been licensed, many fimes companies formed by the inventors themselves for the sole purpose of bringing the embryonic technology developed and fostered here at the University to commercial practicality. Some such case histories follow:

SYNCHROM -- Dr. Fred Regnier, a Purdue staff member, is an expert in enzyme immobilization, and he has done outstanding basic work in this field. With the assistance of Purdue Research Foundation, he was granted United States Patent No. 3, 983, 299, entitled "Bonded Carbohydrate Stationary Phases for Chromatography," which was assigned to Purdue Research Foundation, and then Dr. Regnier and his colleague, Dr. Shung-ho Chang, also were granted United States Patent No. 4, 029, 583, entitled "Chromatographic Supports and Methods and Apparatus for Preparing the Same."

The Foundation, as the licensing agent for Purdue University, sought licensees for the new technology described in these patents. Eventually a lab assistant of Dr. Regnier, Karen Gooding, and her husband; David Gooding, requested a license under the above technology which they would use to start their own business. Karen and Dave formed their own new corporation which they named "SynChrom," accepted a license on the above technology for a certain field of use for a product they expected to sell, and have since built a small manufacturing facility (about 20 feet) and have started to sell a product which embodies the licensed technology.

We believe that, without patent protection, this fledgling business would have very little chance of success because of the threat of a large corporation taking over their product line once they have demonstrated commercial success. As long as these patents remain viable, the business may be expected to flourish.

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Senator Nelson Page 3 April 20, 1978

ROVAC -- In 1969 a graduate student at Purdue, working with a heat transfer problem, conceived what he thought to be a new design for a compressor that would have cooling applications in the automotive industry. The new design was thought to be inefficient for automotive uses. Nevertheless, Purdue Research Foundation agreed to provide limited funds for further work at Purdue, and to patent this device if the inventor could prove that it worked. erica kialawa ambaja ili jali je

To make a very long story short, the device did work, basic United States Patent No. 3, 686, 893 was obtained on the device by Purdue Research Foundation. We contacted over 75 companies, both large and small, and no one was interested in licensing the technology. Finally, an exclusive license was granted the inventor and he formed his own company, to see if he could attract the necessary venture capital to perfect the device and to bring it to market.

At the present time, this company is marketing prototypes of the device, and it has raised over \$10,000,000 in venture capital based on its package of technology which is protected by the basic patent mentioned plus patented improvements.

The only real protection this small company has from a raid and possible technology takeover by a large corporation is the company's patent position and exclusive license agreement with Purdue Research Foundation.

13 HW 06 (6) One of the concerns of the risk capital venturers in the company stock from the beginning has been the strength of its patent position and the licensing arrangement with Purdue Research Foundation.

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A copy of an article in the August, 1977, Forbes magazine about Dr. Edwards and ROVAC is attached to this letter, as well as a copy of the corporation's latest annual report.

AMOS -- One of our staff members, Dr. L. Steven Beckham, invented a new device called "Adjustable Unit for Spiral Separator Seed Processing Machine, " upon which a patent is pending filed by Purdue Research Foundation. Dr. Beckham thought his device had great potential and, since the work required was more developmental than basic, the proper avenue for performance of his work seemed to be outside the University. Therefore, he incorporated Ag-Machinery & Safety, took in some other investors to raise the necessary venture capital, once he was sure that he would have a license from the Foundation to practice the invention, and proceeded to have the device manufactured, and he has been selling this grain separator. When the analysis of the second second second

Senator Nelson Page 4 April 20, 1978

We have been advised that the venture has been a commercial success, and Dr. Beckham has also licensed other University technology, entitled "Ducted Grain or Material Ladder for Top Unloading of Storages and Vessels," upon which the Foundation has filed for a patent, which grain ladder may be used both in conjunction with the spiral separator or as a separate item of commerce. We feel that Dr. Beckham's company's ability to obtain venture capital related, at least in part, to his company's position as the exclusive licensee of Purdue Research Foundation. Both the spiral separator and the grain ladder are fairly simple to construct and would not be difficult for a competitor to copy.

Again we feel that the patent position established by the Foundation, and the position of Dr. Beckham's company as an exclusive licensee for the technology, helps assure his continued commercial viability in a highly competitive market.

A sample of Dr. Beckham's advertising literature is attached simply to illustrate the type of product being sold under exclusive license from Purdue Research Foundation.

In conclusion, I hope that this response will illustrate the fact that embryonic technology developed at the University has been brought to commercial use by the technology transfer program administered by Purdue Research Foundation on behalf of Purdue University, and it should be pointed out that if a government-wide institutional patent agreement were adopted such as proposed in the Federal Register, the technology transfer mission of the University would be greatly simplified and more technology would probably be brought to the consuming public at an earlier time than might otherwise be the case when petitions for greater rights, requests for transfer of title, and the like must be dealt with agency by agency under existing patent statutes, regulations, and policies.

It should be pointed out that none of the three small businesses described above are licensed under technology that arose at the University out of research done with U. S. government funds, but the principle is the same, and the technology transfer program would be the same, but for the many disabling strings referred to above that must be dealt with on an agency by agency basis whenever federal funding is involved. It should also be noted that we do have other examples of government funded research that has produced patentable inventions that have been licensed both to large and small corporations, with notable exceptions being those agencies that have a strict title reservation policy, and inventions that come out of that type of research usually end up

Joseph od Habed Popola Broken Jaja 1978 Senator Nelson Page 5 April 20, 1978

being among those 27,000 U.S. government patents referred to above and appelling a partitional patents of the about 1 and 1

We hope this response will be beneficial for your Committee in its deliberations.

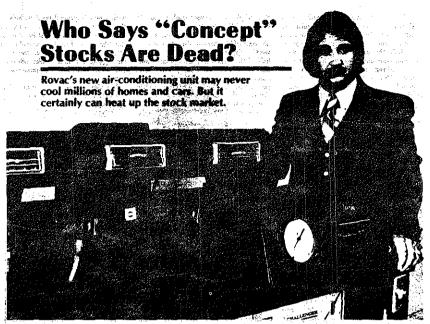
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Dejà Vu: Tom Edwards and his new air conditioner add up to a hot concept stock—just like the good old go go days.

By PHYLLIS BERMAN

In the brand-new headquarters of Rovac Corp. in Rockledge, Fla., there is one empty office. One day—maybe—it will be occupied by the marketing director.

Why is it empty now? Because Rovae, one of the few but-concept companies to come down the pike since the gago days of the Sixties, hasn't a marketing director and has yet to market a single product—or even. It appears, to identify its market. Yet its stock, book value 50 cents, sells for about \$20 and the company's total market value is nearly \$100.

Rovac is having a lot of trouble even getting its product to work well, and it has already had troubles with the Securities & Exchange Commission over its money-raising tactics.

A concept it has, though. In brief, it is this: Rovac has the technology for an air conditioner that uses air and water rather than Freen as a remgerant. Freen, or course, has been damned by the National Academy of Sciences as a

threat to the ozone layer. That's the reason the Environmental Protection Agency has proposed banning some Freon aerosol propellants. Freon is also the cooling agent in most existing air conditioners. So, if Freon-propelled shaving cream is out today, the reasoning goes. Freon air conditioners could be gone tomorrow. And Rovac's air conditioner is the only feasible non-Freon one on the horizon.

There is just one hitch in this happy story: The Feds may have no intention of banning Freen as a refrigerant. Says an EPA chemist, "I don't think it will ever come to that." Rovac contends that even so, its system is more efficient and cheaper than conventional models. But without the aid of law, Rovac may never get off the ground.

It's a long way from a concept, no matter how brilliantly conceived and sable, to a product that can be mass-produced. So tar. Howe has produced only a dozen au-conditioning machines, all of them by hand.

So what makes it, as a company, worth

5100 million? A story, that's what. Remember what a hard time Chester Carlson had until Halbid (now Xerox) bought him out? How much money has been lost chasing the will-of-the-wisp of "another Xerox?"?

The Rovae circulator is the brainchild of Thomas C. Edwards, 34, the company's president and founder, an amiable and enthusiastic mechanical engineer. Like all mechanical cooling systems, the machine works by compression. But Edwards uses air and water—rather than Freon in the pipes over which the air passes—as the actual cooling medium (using some of the same principles in air-cooled aircraft

Edwards developed his device that is the heart of his technology for a high school science fair project 17 years ago. Ten years later he used it for his PhD thesis at Pardue University. Then he put it saide for fiver years to teach college, but couldn't get it out of his mind; so he obtained 315,000 in 1972 and set up Rovae for Rotary Vane Air Cycle).

Touring the East Coast with a slide show, Edwards was able to raise another \$500,000. It was hardly enough to perfect and manufacture his design, so in 1974 the brash little company went public-no mean feat in that bear market-raising another \$2 million. The price: \$5 a unit. "How did they do it?" asks Edwards first underwriter, Stanley Morgenstern of New York City-based Bond, Richman & Co. "The question is how did I do it? It was a hard sell, believe me.

That was enough money for Edwards to deliver prototypes to General Motors, Ford, Fiat, Chrysler, the Army and the Air Force. They made an unbearable noise and were too heavy. To debug them. Edwards needed more money.

Enter Allen & Co., the wheeler-dealer investment bankers famed as the sponsor of another hot-technology company, Syntex. The pioneer in hormones for use in contraceptives, Syntex was a spectacular growth stock of the Sixties. Allen offered a private placement in February for Royac that will bring it up to \$3.5 million, enough to produce 1,000 units a month.

Bernard Stein, the Allen vice presi-dent who handled the deal, says: "What we were looking for was another Syntex. We told our investors, It's a great crap shoot. You could lose everything...[but] theoretically you could invest \$4.50 and get back \$1,000." Among the people who took a chance at \$4.50 for a go at \$1,000 were people like movie producer The series of th

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general and the

Ray Stark and former ambassador to Cuba Earl E.T. Smith.

Meanwhile. Tom Edwards was selling off some of his shares-almost \$1 million worth. He still has slightly more than half of the nearly 5 million shares outstanding. That's \$1 million in his bank account and another \$50 million on paper. Exults Edwards: I'm very certain this is another Xerox or Polaroid.

Hardly less enthusiastic is E.E. (Buzz) Geduld of Jersey City's Herzog, Heine or Co., which makes a market in Royac stock. "It's a concept," he says, "and

"... 'Concepts move stocks. It's not technical. [Anyone] can understand it' . . ."

concepts move stocks. It's not highly technical. You can understand it. I can understand it. That's why the little guy buys it."

What is the "little guy" buying? A stock with a book value of just 56 cents a share.

No sales. No earnings. No products. No clear marketing plan for applica-tions. (Inventor Edwards has tackled the original-auto-equipment market, the truck-cab food refrigeration market and the housing market. Now he's tackling the auto market again-only this time

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with a new improved version, he's after the consumers, not the prox in Detroit Add to this a couple of brushes with

the SEC-the first for overselling the original private placement, the second for rigging the first public offering in 1974, both settled by a promise not to do it again.

In a single hour last December Royacdropped from \$30.50 a share to \$13.50 for no apparent reason. The stock recovered the same day to \$20, about where it stands today.

Meanwhile, Royac is about to go back to the well for more money. Edwards says he favors a public offering. Allen & Co. says it would prefer a loan, to avoid further diluting the equity.

Royac could be another Xerox. On the other hand, whenever we hear about stocks selling at fancy prices when the company doesn't even have a marketable product yet, we are reminded of the one about the farmer who bought a barrel of oysters for an irresistible \$2. "What's that you got?" asked a friend. "Oysters, got 'em for \$2 the barrel," said the farmer. That's a fine price. I'll give you \$4 for em. said the friend. And so it went, until the oysters finally changed hands for \$40. When the purchaser opened the barrel. he found the oysters were inedible. Mad as hell, he pursued the chain right back to the original seller, who turned out to be a canny old sailor in a scaport.

Them weren't eating oysters," explained the sailor. "Them are selling oysters."

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March 1, 1978 ... 263-2831

Mr. Stuart E. Eizenstat Assistant to the President Assistant to the President
for Domestic Affairs & Policy
The White House
Washington, D. C. 20500

Dear Mr. Eizenstat:

Having actively participated in the meeting of January 17, 1978 between, on the one hand, the President of the Universities of Minnesota, Purdue, ... Rochester and Virginia representing the Association of American Universities, representatives for the American Council for Education, and the Committee on Governmental Relations, National Association of College and University Business Officers and, on the other hand, Mr. Malson of the Domestic Policy Staff and Mr. Hartke of OSTP, I was cognizant of the concerns of the Administration in esponsing a particular Federal patent policy.

As the newly elected President of the Society of University Patent Administrators (SUPA) I conveved those concerns to the members of our Society and, on behalf of the Society, desire at this time to endorse the position and the of the University sector which was set forth in the recent communication. to you from the American Council for Education and sister organizations,

Since that position paper did not analyze in detail some of the fundamental reasons for reaching the conclusions expressed, and since SUPA believes that such an analysis is an important element for use and for the record in the current deliberations on Federal patent policy and may, as well, be onlightening to those who are less familiar with intellectual property and 2000 the transfer of technology, you will find in the enclosed paper a discussion of the analytical basis for the position of the University sector and its support of the Thornton Bill, H. R. 8596.

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Mr. Stuart E. Eizenstat

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Although all of the conclusions that have been reached in the attached paper are not documented by statistical evidence, or with all the data that might be desirable, we are also fully aware that the proponents of the title-in-the-government position are also not bolstered by any such data. Where, in the analysis, reference has been made to certain studies which have been conducted we firmly believe that those studies uniformly support the H.R. 8596 approach. In addition, the analysis reflects the experience of persons who have been extensively involved in the technology transfer process and comports with my personal views which have been generated over a period in excess of 17 years as Patent Counsel for the Wisconsin Alumni Research Foundation, the patent administration and technology transfer agent for the University of Wisconsin. Above all, my personal experience has indicated that the title-in-the-government. approach is a tremendous disincentive to the successful transfer of technology to the public for its benefit and, in fact, functions to stifle and the development of new technology,

In addition to the attached paper we call your attention to a recent article in the February 20, 1978 edition of Business Week by Rimmer de Vries which points out that the fundamental problem with the depreciated dollar is the need for a national export policy and specifically states "We have to develop new technology and go out and sell the stuff," A recent article in the American Bar Association Journal by Sheila McLean is also of interest since it focuses upon the various arrangements which, through the patent system, can serve the public interest. Copies of each of these are also attached.

We strongly urge you to give your close and eareful attention to the enclosed analysis, which we believe is objectively presented; and particular regard to our reasoned concern that there is a strong probability that maintenance of the "status quo" is likely to ultimately result in Government patent policy moving further in the direction of title-in-the-government. It is the studied conclusion and strong belief of SUPA and its individual members that if such policy becomes prevalent the industrial sector's effectiveness in sensing the needs of our society and introducing new technology to meet such needs would be severely and adversely impacted and start our country on the road to mediocrity.

which share the earl off office again Very truly yours,

HWB;rw

Howard W. Bremer President, Society of University Patent Administrators



Four by Five, Inc.

Recent negotiations between nonprofit, "public sector" institutions and commercial, "private sector" firms concerning patent arrangements exemplify how the patent system can serve the public interest. Experiences of the Population Council and the Ford Foundation in negotiating patent rights for contraceptive developments under grants they made are interesting precedents for further collaboration.

By Sheila Avrin McLean

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IN RECENT years the patent system in the United States has been the subject of frequent, critical examination. T.L. Bowes's December, 1975, American Bar Association Journal article, "Patents and the Public Interest" (61 A.B.A.J. 1521), usefully summarizes this controversy surrounding our patent system and concludes that the system has served the public interest by helping "this nation become a pre-eminent developer of technology." Some recent negotiations between nonprofit, "public sector" institutions and commercial, "private sector" firms concerning patent arrangements provide an instructive new model of how the patent system can serve the public interest by catalyzing the further development of nonprofit-based research and technology.

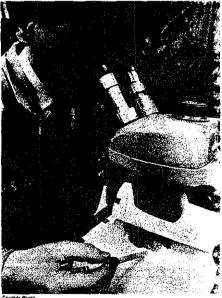
It is important to recognize that collaboration between the private and public sectors is increasingly

Authors Note: This article is based on a report prepared for the Reproductive Biology and Contraceptive Development project under the direction of Roy O. Greep, Laboratory of Human Reproduction and Reproductive Biology, Harvard School of Medicine, which was approared by the Ford Foundation. The views expressed in this article are those of the author and do not represent an official policy of the Ford Foundation.

essential to the development of products that are ultimately useful to the public. Carl Dierassi, a founder Syntex and now a Stanford professor, forcefully pointed out seven years ago in Science that while many basic discoveries and important steps leading to technological developments are made by researchers based in the nonprofit or public sector, pharmaceutical firms—private sector firms—"play an indispensible role in the development of any drug." His observations have been reinforced by a 1974 report prepared for the Federal Council for Science and Technology, which reflects the obvious point that universities and nonprofit hospitals do not engage in direct manufacture. Thus, industry must bring university inventions to the market place.

Since collaboration is so essential, consideration of new arrangements for bringing the private and public sectors together for their mutual benefit may be helpful to lawyers advising either sector. Some experiences of the Population Council and the Ford Foundation in negotiating patent rights for contraceptive developments under grants they had made serve as interesting precedents for further collaboration in that and other areas.

Inventions in the field of contraceptive research illustrate the way in which patented technology is often



Candida Photo

Patents and Collaboration

developed. Individual university-based researchers may conceive of new ideas for fertility-regulating drugs or devices or combinations thereof. Through their universities, they receive initial "seed" funding from governmental or philanthropic agencies. But to some extent the invention and to a greater extent the necessary initial research are done at organized laboratories by teams of professionals associated with medical schools, research hospitals, or nonprofit research institutions. The inventor-professor usually is required by employment arrangements to convey patent rights to the employer-university, at least in part. The work in the nonprofit sector typically does not result in a product that can be distributed to the public. Additional research and much of the necessary development is done by specially trained teams at wellequipped laboratories, frequently those maintained by profit-oriented pharmaceutical firms. This is particularly the case when development of the invention requires the Food and Drug Administration's approval, necessitating extensive and costly clinical testing.

In these cases there is a potential for conflict between the public and private sectors in the differing philosophies underlying the funding of research by public sector organizations, the availability of patent protection for new inventions, and the further funding provided by the phermaceutical firm. The public sector donor proceeds on the premise that its reward for helping to finance an invention will be public access to the results of the supported research at minimum expense. The patent laws, on the other hand, are based on the philosophy of encouraging the development of new ideas by giving the inventor the right under a patent for a limited period to profit from the invention—either by use of the patent or through royalty arrangements with others. Because an inventor may choose to obtain patent protection in more than one country, it is possible to obtain virtually worldwide patent rights for an invention, albeit for limited periods of time.

Marketing Creates Interest in Royalties

Simply stated, if a patented invention is marketed, several parties involved in its development—the university or hospital where the original research was conducted, the investigator (inventor) in whose name the patent was prosecuted, and the pharmaceutical firm where further research and development are carried on—become interested in royalties under the patent and in the exclusive right to control the manufacture and sale of the product.

The public sector donor [for example, the Population Council, the United States Agency for International Development, or the Ford Foundation) usually retains some form of license—usually a royalty-free, nonexclusive license to make, use, and sell the invention—but it is usually impractical for these funding agencies to consider exercising this license. Not being in the busi-

ness of manufacturing and not typically in the business of distributing drugs or devices, they must develop alternatives to safeguard their original purpose of public sector access, at low cost, to the patented invention they helped to finance.

Experience has shown that in exchange for providing venture capital and other support for further necessary research and development, pharmaceutical firms are likely to require an exclusive license under the patent-the exclusive right to make, use, and sell the new invention. Sometimes working together, and sometimes separately, the Population Council and the Ford Foundation have developed with pharmaceutical firms an interesting and innovative approach to this espect of patents under research grants. At the stage when a great for research is made, the grantee institution (usually a university) and the principal investigator enter into a patent agreement with the foundation or council under which the institution or investigator is responsible for obtaining patents on inventions and may grant only nonexclusive licenses of any patentable invention resulting from the sponsored research. The agreement requires the foundation's or council's consent before the institution or investigator may permit an exclusive license of the patent. Drug companies interested in further development and marketing of the invention usually do request the foundation's or council's consent to exclusive licenses before they will make the substantial investment to develop, test, and market the drug or device.

Royalties Can Be Fed Back into Research

The foundation and council have made an initial decision not to demand royalties in return for the consent to an exclusive license, even though it might be simpler to negotiate standard royalty arrangements with pharmaceutical firms. The donor agencies could then feed these royalties back into further research. The Population Council, for one, has considered and rejected this approach on the ground that its objectivity in advising on the use of contraceptives might be impugned if it were viewed as having a financial stake in a particular product.

Instead they take steps in their agreements with the drug companies to assure that the public sector will be able to purchase the new contraceptive devices at a price lower than that which the drug company would charge the private sector (for example, commercial suppliers to private physicians). The key issues forming the basis of these agreements are (a) definition of the "public sector," (b) pricing formulas, and (c) guaranty of supply to the public sector. "Public sector" is defined, for example, as national and voluntary family planning programs. A pricing formula for the public sector. For example, may take into account the cost of the product to the pharmaceutical firm but not give any profit to the firm from public sector purchasers. The guaranty of supply provisions attempt to assure

de atticue propri augusto Albertas that public sector agencies that order the product at the special public sector price will have it supplied to

The details vary with circumstances, such as the sums of money the various parties have contributed, or will have to contribute, to research and development. Negotiating these arrangements can be extremely complex and time consuming, and the legal fees can be substantial. There are at least four parties-the donor agency, the hospital or university in which the inventor works, the inventor, and the drug company. The interests of the various parties are not, of course, identical. The hospital and inventor usually work out royalty arrangements at the same time the donor agencies negotiate the special public sector pricing formula. But if the parties approach the negotiations in good faith, and with a sense of humor, their agreement can be a workable model for collaboration between philanthropy and industry.

Justice Department Issues Position

The Justice Department has recently announced its position on a patent licensing arrangement between a nonprofit, public sector organization and several private sector pharmsceutical firms. The public sector concern is the Salk Institute for Biological Studies, a publicly supported, nonprofit organization in California that performs biological research. Salk outlined to the Justice Department a proposed licensing arrangement of patents for a drug (Somastostatin) intended to treat diabetes. Salk would grant world-wide, nonexclusive patent licenses to five pharmaceutical firms and would also agree not to grant additional licenses for a period of three years after the first sale of the drug. At the end of three years Salk would again be free to grant additional nonexclusive licenses. In return, the phermaceutical firm licensees would pay the institute royalties and would commit themselves to clinical testing necessary to obtaining the Food and Drug Administration's approval to distribute the drug,

In February, 1975, the Antitrust Division of the Justice Department issued an unfavorable business review letter with respect to these proposed arrangements. But in December, 1975, the division reversed its earlier position. In the December letter, it found that temporary limitation of the number of licensees appeared reasonable because Salk had been unable to obtain license agreements with qualified and interested firms without such a limitation. In addition, the division found that the terms in Salk's licensing agreement were designed to minimize the anticompetitive consequences of that limitation.

This discussion of patents has focused on public access to petented inventions initially funded by the public sector. It is important to remember that the life of patents is limited in the United States for seventeen years. Indeed, some of the patents on contraceptives invented in the late 1950s and early 1960s have expired

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Shaile Aven Mel een is seendiste general counsel of the Ford ndetion. A former me of the Executive Committee of the Association of the Bar of the City of New York, she was (A.B. 1983) and Yale Law Scho



or are about to expire. For example, Syntex's patent on Norethindrone and Searle's patent on Norethynodrel expired in 1972. Once the patent expires, the invention, including all the data related to it contained in the patent application, is dedicated to the public.

In certain cases the patent holder and those with licenses to make the invention will have a large head start in developing technical know-how and market acceptance for the product, and their market position may not be affected adversely by the expiration of the patent. This may be true for patented devices such as intrauterine devices carrying releasing compounds. On the other hand, replication of available contraceptive compounds used for the female contraceptive pill is relatively simple and inexpensive. The end of patent protection on these products will almost certainly invite competition and reduce the monopoly profits assured by the patent.

Life of a Patent May Be Extended

Because the Food and Drug Administration and other regulatory requirements demand a lengthy period of testing before a patented product can be approved for general use, Carl Dierassi has suggested that the life of a patent be extended for a specified number of years after a contraceptive product has been approved by the regulatory agency. Congressional consideration might be given to granting these extensions. by amending the patent law, in return for a quid proquo benefiting the public, as, for example, a stipulation that the product be made available at a special low price (at "cost") to nonprofit or governmental programs distributing the product (nonprofit government sponsored family planning programs).

As indicated by these examples, imaginative use of patent arrangements can facilitate the developmentand marketing of public sector inventions by collaboration between the private and public sectors despite the differing interests of the parties involved. The suggested model may encourage other public funding agencies, universities, nonprofit research institutes. and private, profit-oriented companies-and their legal counsel-to look at their negotiations over patent rights as a helpful tool for mutually beneficial collab-

oration.



Interview with Rimmer de Vries

THE NEED FOR A POLICY TO BUILD EXPORTS

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